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No. 80-742

In the Supreme Court of the United States

OCTOBER TERM, 1980

NATIONAL PORK PRODUCERS COUNCIL, CHARLES GRASSLEY, THOMAS HAGEDORN, and STEVEN SYMMS,

Petitioners,

vs.

BOB BERGLAND, Secretary of Agriculture, CAROL TUCKER FOREMAN, and DONALD H. HOUSTON,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE COURT OF APPEALS FOR THE EIGHTH CIRCUIT

DONALD P. COLLETON
Counsel of Record

JAMES L. FOX
ABRAMSON & FOX
One East Wacker Drive
Chicago, Illinois 60601
(312) 644-8500

Attorneys for Petitioners

UNITED STATES LAW PRINTING CO., CHICAGO, ILLINOIS 60618 (312) 525-6581

QUESTIONS PRESENTED FOR REVIEW

Whether the court of appeals in its review of United States Department of Agriculture rulemaking has itself, in disregard of *Overton Park**, arbitrarily exposed the American consumer to the deadly hazards of botulism.

Whether USDA exceeded its authority in promoting sales of unpreserved foods through a rule which needlessly jeopardizes public health.

Whether the decision below permitting USDA to omit assessment under the National Environmental Policy Act of a department rule's public health impact conflicts with the construction placed on NEPA by other circuits and if so whether this Court should resolve the conflict.

PARTIES

Petitioners

National Pork Producers Council
Charles Grassley M.C.
Thomas Hagedorn M.C.
Steven Symms M.C.

Respondents

Bob Bergland, Secretary of Agriculture

Carol Tucker Foreman, Assistant Secretary of Agriculture

Donald H. Houston, Acting Administrator of the Food Safety & Quality Service within the Department of Agriculture

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* *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971).

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VS.

BOB BERGLAND, Secretary of Agriculture, CAROL TUCKER FOREMAN, and DONALD H. HOUSTON,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE COURT OF APPEALS FOR THE EIGHTH CIRCUIT

TO: The Honorable Chief Justice of the United States and the Associates Justices of the Supreme Court of the United States:

Petitioners respectfully pray that a Writ of Certiorari issue to review the opinion of the United States Court of Appeals entered September 23, 1980, reversing the permanent injunction of the district court in Des Moines.

OPINIONS BELOW

The district court's opinion is published at 484 F. Supp. 540 (S.D. Ia. 1980). The opinion of the court of appeals has not been officially published. Both opinions appear in the Appendix.

JURISDICTION

The decision of the court of appeals was entered on September 23, 1980 within ninety days of which this petition has been filed. Jurisdiction in this Court is invoked under 28 U.S.C. §1254(1).

STATUTORY PROVISIONS INVOLVED

This petition involves:

9 C.F.R. §§317.17(b) and (c) and 319.2

5 U.S.C. §553

5 U.S.C. §706(2)(A)

42 U.S.C. §4332

40 C.F.R. 1501.4(c) and (e) and 1508.13

These provisions appear in the Appendix.

(Emphasis added throughout unless otherwise indicated)

STATEMENT OF THE CASE

Proceedings and Jurisdiction of the Court Below On September 20, 1979 the NATIONAL PORK PRODUCERS COUNCIL and three United States Congressmen brought suit in the Southern District of Iowa to enjoin, as arbitrary and capricious, a United States Department of Agriculture (Department) labeling regulation, 44 *Fed. Reg.* 48959-61 (August 21, 1979), 9 C.F.R. §317.17(b) and (c) and

§319.2 (the Rule), App. 91-93, which permits nitrite-free foods to be sold under the guise and name of traditional nitrite preserved foods. Jurisdiction was invoked under 21 U.S.C. §674, 5 U.S.C. §§701-706 and 28 U.S.C. §1331, 1332, 1337 and 2201-2202. On February 12, 1980 the district court permanently enjoined enforcement or application of the rule. App. 21-47. The government appealed basing jurisdiction for appeal on 28 U.S.C. §1291. On September 23, 1980, a panel of the Eighth Circuit reversed, App. 1-20, but upon petitioners' motion has stayed issuance of its mandate pending consideration of the case by this Court.

THE FACTS

A. Botulism and Nitrite

Clostridium botulinum, a bacterium considered present in all raw foods, produces a deadly toxin known as botulin in a short period of time at elevated temperatures in the absence of molecular oxygen. When added to food as a preservative, nitrite salts have proven highly effective in inhibiting the production of botulin in meat products. As a result popular nitrite-cured products such as frankfurters, cold cuts and bacon can be and are sometimes, perhaps often, handled safely in unrefrigerated ways which without nitrite could promote the formation of botulin.

B. The Rulemaking

On April 28, 1978 the Department's Food Safety & Quality Service proposed the challenged Rule, App. 52-59, in response, according to the Court below, App. 13-16, to suggestions by some that "nitrite-free products were difficult to locate or not available." App. 15. Under the proposal, nitriteless meat products could have the same

flavor, consistency and name of meats preserved with nitrites provided labeling disclosed the absence of nitrite and called for refrigeration below 40° F.

The proposal drew 365 comments. Among others, these concerns were expressed:

> (1) The proposed cautionary labels will not be read at all by many. A variety of reasons for this was suggested. Some habitually do not read labels. Others, because of illiteracy, old or young age or language barriers, cannot read them. The presence of familiar color, form, and texture, coupled with the common name, will implicitly persuade still others that the product is the familiar one and hence there is no reason to search the label for new, special handling instructions.
>
> (2) Some who read the label will not understand the disclosures.
>
> (3) Some who read and understand the label disclosures, will, not unreasonably, be skeptical because everything else about the apparently familiar product will seem to contradict the warning.
>
> (4) Consumers will be greatly confused.
>
> (5) Because many consumers have long learned practices of handling cured products in ways that would be hazardous without nitrite, the proposed label disclosure will not suffice to protect against botulism. As a result, the Rule will injure consumers and the entire meat industry.

See, e.g., Comments 97, 130, 169, 174, 175, 182, 186, 190, 197, 199, 206, 252, 253, 257, 258 (App. 60), 260 (App. 65), 273, 280 (App. 70), 290, 291, 298, 324, 329 and 352. The same concerns were later reiterated at a meeting of the Department's Meat and Poultry Advisory Committee, attended by respondents Houston and Foreman.

To illustrate, a public interest group wrote:

"The consumer who is accustomed to leaving cold cuts or frankfurthers exposed and is uncautious with leftovers is unlikely to change his or her habits when presented with what appears to be the same product, with the addition of a warning label.

The required duplication of the original product in color, form and texture, coupled with the use of the same product name, will promote acceptance; the consumer's *familiarity* with the product, however, *will reduce the likelihood that the label will be read* for new requirements of product use.

"Assuming the label is read, there is the added problem of *consumer skepticism or indifference.* Products which have been widely used and accepted have suddenly been proclaimed 'unsafe' and a rash of new warning labels have appeared. The result is that the labeling device is losing credibility, as is apparent with cigarette and saccharin warnings. Where there is no apparent product change, the consumer may ignore any warnings or directions on new use or new dangers of products, assuming that they are merely new warnings attached to an old product which they *know* how to use.

• • •

"The proposed rule would allow both the product cured with nitrite and the product preserved without or with low levels of this substance to be available to consumers, and to be marketed under the self-same name. The *potential for misuse and confusion* seems obvious where consumers are confronted with two products which are virtually indistinguishable but demand different use habits.

"The marketing of both meat products under the commonly-used name may increase the risk of botulism and other diseases. A higher incidence of botulism exists in countries which do not cure meats with nitrites . . . The confusion resulting from two prod-

> ucts with *different* use requirements but the same product name might even compound the botulism problem, with consumers being less cautious than where only a nitrite-free product is available. In addition, the packaging will become separated from the food product. As a result, *leftovers and/or products stored out of their original packaging will give no warning* of the procedures required to avoid risk. The effect of the proposed rule may therefore ultimately be a reduction in confidence and consumer use of *both* the nitrite-free produce *and* the nitrite-cured product." Comment 260; App. 65-69

Notably, while commentators familiar with nitrites or desirous of avoiding foods containing them, suggested that *they* would read the proposed labeling instructions, few contended directly that these instructions would in fact be read by all or most consumers. The rulemaking record contains no professional or expert studies, testimony, comment or analysis of any kind establishing the fact, likelihood or even possibility that the warning labels would be generally read, understood or believed by ordinary consumers, apart from those interested in the current nitrite controversy.

Notwithstanding the concerns expressed, the Rule for labeling unpreserved meats, as proposed, was adopted on August 21, 1979 with the added requirements that nitrite-free meats be *similar* to preserved meats *in size and general appearance* and, as originally proposed, in flavor and consistency and that the term "uncured" precede the traditional name. App. 91-93. That term, according to the rulemaker, is "commonly understood" to mean that the product does not contain nitrite. App. 85.

Neither the preamble to the Rule nor the Rule itself addressed the concerns, listed above, of commentors and the Committee other than to note that questions had been

raised about the adequacy of the proposed warning labels and to observe, without explanation, that the Administrator

> "is aware that the products requiring such special handling such as pork sausage, bratwurst and bockwurst have presented no apparent health hazards even though prepared without nitrates or nitrites and marketed unfrozen. He concludes that consumers have demonstrated a knowledge of the handling practices necessary for any of such products prepared without nitrates or nitrites and that the prescribed labeling for such products, i.e., "Not Preserved—Keep Refrigerated Below 40°F At All Times", will adequately inform the consumer of *how* to maintain such products in a wholesome condition until consumed." App. 86-87.

C. The Rulemaker's Explanation

In the course of the district court's review, the government explained the challenged rulemaking through Irwin Fried, the Department employee who supervised the administrative proceeding. His explanation ran as follows:

> 1. It is true "that nitrites have been found to prevent the growth of *clostridium botulinum,* a natural contaminant of improperly preserved meat products, and which produces an extremely potent poison usually fatal to man; that there are no substances that could be utilized under sufficiently broad scale to prevent botulism in commercially processed meats" and that "*without nitrites*" "[*c*]*ommon usage* of such products as hot dogs and ham would *not* be *possible without severe health hazards.*" Tr. 146, App. 95-96.
>
> 2. He would agree that "*not* too *many* people *read . . . handling instructions*" but instead rely on "previous experience." Tr. 195; App. 97-98.
>
> 3. His basis for believing consumers will read the label prescribed by the Rule [the *sole* means proposed by the Rule to distinguish an apparently nitrite-pre-

served from a nitrite-free product] is "everything that we have received . . . from *people who want* to have *nitrite-free* products." Tr. 197, App. 98.

4. *No consideration* is given in the Rule as to how consumers are to be protected from the hazards of nitrite-free products which look like traditional nitrite-preserved products when

a) the prescribed label is removed.

b) the nitrite-free products are sold in bulk as in delicatessen sales when bologna is hand-sliced and wrapped.

c) the nitrite-free products are "displayed in the old-fashioned cases with the butcher behind and there are no labels on the product."

d) the consumers are non-English speaking.

e) the consumers are functional illiterates. Tr. 142-3, App. 94-95.

5. *Not "everybody" will understand* what the term "uncured" (as required by the Rule to alert consumers to the nitrite-free character of what appears to be a traditional nitrite-preserved product) means. Tr. 192, App. 96.

6. He does *not know* whether the meaning of "uncured" would be understood by functional illiterates, non-English speaking consumers or children. Tr. 192-3; App. 96-98.

D. Final Impact Statement

A Final Impact Statement (FIS) for the Rule, App. 72-82 disclosed in a note to the final Rule, App. 93 showed:

(1) some 34 establishments market nitrate and/or nitrite-free processed meat products under 168 different product labels.

(2) the Rule was expected to advantage nitrite-free product manufacturers by facilitating development of their markets.

(3) the Rule was not expected to result in any increase in the incidence of types A and B botulism because "these types do not generally grow at temperatures below 40°F."

The FIS also noted concerns expressed in the Comments about consumer confusion between nitrite-free and nitrite-preserved products and about

> "the possibility that abuses could occur because of . . . careless food handlers . . . and food taken on picnics, to work, and to school."

The FIS did not undertake to answer these concerns.

E. The District Court's Review

Confining its review to the administrative record and the explanatory testimony offered by the government, the district court set aside the Rule on four grounds:

(1) a lack of rational basis in the record for the conclusion that ordinary consumers, faced with a long-established product and a new product which differ only in the information on its label, will distinguish between the two and a failure by the Department adequately to consider relevant factors regarding consumer conduct in reading labels and caring for nitrite products and the resulting danger of botulism from similar handling of nitriteless products. App. 29-32.

(2) lack of Department authority to enact a rule solely to facilitate markets of uncured producers at the expense of producers of cured products. App. 36.

(3) lack of Department authority to impose the similarity requirements and subjective flavor standard contained in the Rule. App. 36-41.

(4) failure to comply with the requirements of the National Environmental Policy Act in that the Department neither filed nor considered the need to file an Environmental Impact Statement. App. 44-47.

F. The Circuit Court's Review

The court of appeals reversed, concluding that:

(1) the Department adequately considered the risk of botulism and the efficacy of the required labeling

(2) the Department's purpose in adopting the Rule was to expand the availability of nitriteless products, and that this purpose, when accomplished "in a form and manner consistent with the public health and welfare", was lawful, and that the Rule bears a rational relationship to this purpose

(3) the similarity and subjective flavor requirements are lawful

(4) the agency considered the Rule's potential for significantly affecting the quality of the human environment and properly found no such effects.

REASONS FOR GRANTING THE WRIT

Courts should generally leave regulations to the regulators. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519 (1978). When, however, regulators substantially omit the key issue inquiry and analysis required for rational rulemaking, Congress has authorized judicial intervention, not to rewrite bad rules but to shield the public from their arbitrary effects. *Citizens to Preserve Overton Park* v. *Volpe,* 401 U.S. 402 (1971). When the impact of deficient rulemaking is life-threatening, this Court is the public's last but most necessary protection. The presently challenged Rule, by arbitrarily exposing consumers to botulism food poisoning, is such a rule and, therefore, warrants this Court's scrutiny.[1]

I.

The Department's Disregard of Relevant Factors Violates the Requirements of Overton Park and Seriously Jeopardizes Consumer Health and Safety

The most compelling reason for granting the writ is the Rule's jeopardy to human health resulting from manifest

[1] *Citizens to Preserve Overton Park* v. *Volpe,* 401 U.S. 402 (1971) establishes the standards for judicial review of agency action under the arbitrary and capricious standard of the Administrative Procedure Act, 5 U.S.C. §706(2)(A). In making that review, this Court accords no special deference to the decisions of the court of appeals or district court, *Cf. Asarco, Inc.* v. *E.P.A.,* 616 F.2d 1153, 1161 (9th Cir. 1980); *Polcover* v. *Sec'y of Treasury,* 477 F.2d 1223, 1226-27 (D.C. Cir.), *cert. denied,* 414 U.S. 1001 (1973); *First National Bank of Fayetteville* v. *Smith,* 508 F.2d 1371, 1374 (8th Cir. 1974), *cert. denied,* 421 U.S. 930 (1975), but itself makes a fresh determination of whether the statutory requirements have been met.

agency disregard of factors bearing directly on consumer safety.

The Rule permits unpreserved meats to be sold in the marketplace under the names of and in forms visually (size and color) *identical* to preserved meats such as hot dogs, bologna and bacon. Because without nitrites meats support the production of botulin if subjected to the unrefrigerated handling (picnics, overnight camping, school lunching, etc.) associated with the traditional products, the crucial questions in the rulemaking were (1) whether the cautionary labeling prescribed by the Rule for unpreserved meats would be read, understood and believed by ordinary consumers so as to forestall the unrefrigerated use presently associated with preserved counterparts and (2) if not, what increased risk of botulism would result under the Rule. Petitioners contend that contrary to the requirements of *Citizens to Preserve Overton Park* v. *Volpe, supra,* the Department not only gave insufficient consideration to these questions but knew at the time it promulgated the Rule that labeling would not suffice to alter handling practices or remove the danger of botulism. Hence petitioners say the Rule is arbitrary and capricious.

a) Labeling efficacy overlooked

It was no doubt the potential for illness from confusion of look and name alike products that led the rulemaker to consider a requirement for distinctive precautionary labeling in the final Rule. See, e.g., App. 84-85. The rulemaker and the court of appeals, however, did not go on to assess whether that requirement—the sole means of protection afforded by the Rule—would be efficacious under the circumstances mentioned in the Comments. Therein lies the deficiency and health danger of which the present petitioners complain.

More specifically, under the labeling requirement the plight of illiterates, non-English speaking consumers and those with infirm vision—interests clearly present in the consumer body and noted in the comments—arbitrarily was not considered either by the rulemaker or by the court of appeals in its review. Indeed, there is not mere silence on this point, which without more would be a proper basis for setting the Rule aside, *Sabin* v. *Butz,* 515 F2d 1061, 1069 (10th Cir. 1975); *U. S.* v. *Nova Scotia Food Products Corp.,* 568 F2d 240, 251 (2nd Cir. 1977); rather, in "explaining" its position, *Overton, supra,* 401 U.S. at 420; *Camp* v. *Pitts,* 411 U.S. 138, 143 (1973). the Department affirmatively conceded that the final Rule omits consideration not only of illiterates and the non-English speaking but of consumers in general when the precautionary label is removed or the product is sold without labels as through delicatessens. App. 94-95. This failure alone requires reversal.[2]

The Department's analysis of the efficacy of the required labeling in protecting literate, English speaking people when the label remains attached is equally inadequate. The administrative record[3] shows, and the court of appeals and district court found App. 11 and 32, that some commentators said

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[2] Petitioner's do not ask this Court to substitute its judgment for that of the Department. *Vermont Yankee Nuclear Power Corp.* v. *NRDC, supra,* says that where the rulemaker fails to indicate judgment either way or the basis for its judgment on a relevant factor such as protection of large subgroups in the population, the rulemaking cannot be sustained.

[3] The administrative record consists of the April 28, 1978 Notice of Proposed Rulemaking, App. 52-59, 365 Comments, a transcript of the July 18, 1979 meeting of the Department's Meat and Poultry Advisory Committee at which the proposed rule was discussed, the August 21, 1979 final rule and explanation. App. 83-93, and the FIS. App. 72-82.

they acquire knowledge of food products from label reading and

they are willing to follow handling instructions.

These comments came largely if not exclusively from either nitrite-free manufacturers or from individual consumers or professional consumer groups with an active preference for additive-free foods or a professed hostility toward nitrite. See, e.g., Comments 54, 106, 132, 196 and 246 cited by the government in the court below. Indisputably *they* would search out label information about nitrites and safe handling. The relevant question, however, concerned not what those people would do with the cautionary label prescribed by the Rule but what *ordinary* consumers, who consume millions of pounds of hot dogs, lunch meats and bacon daily and who have little or no acquaintance with or interest in the nitrite controversy,[4] would do.[5] The final Rule fails, and petitioners submit,

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[4] If the Department believed the anti-nitrite comments were fairly representative of the ordinary consumer who consumes and wishes to continue consuming traditional, preserved meats, *Overton Park* required a clear statement to that effect and the reasons justifying it in the preamble to the Rule so as to facilitate proper judicial review. The absence here of both precludes this Court from indulging in or sustaining such a belief and thereby the Rule. *U. S.* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240, 251 (3rd Cir. 1977).

[5] The Department official responsible for the rulemaking says his basis for believing consumers will read the label prescribed by the Rule is "everything that we have received . . . from *people who want* to have *nitrite-free products.*" App. 98. No doubt that is true. But the observation only points up more sharply the Department's irrational conclusion that all other people, patently the overwhelming majority of consumers, who are not cognizant of or involved in the nitrite controversy will search out special handling instructions on the labels of what appear to be the same hot dogs and lunch meats they have been purchasing and subjecting to unrefrigerated use all their lives.

fatally, to disclose that the Department made any analysis whatsoever of this factor. *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F2d 688, 701 (2nd Cir.), *cert. denied*, 423 U.S. 827 (1975); *Environmental Defense Fund, Inc.* v. *Ruckelhaus*, 439 F2d 584 (D. C. Cir. 1971); *Angel* v. *Butz*, 487 F2d 260, 263 (10th Cir. 1973), *cert. denied*, 417 U.S. 967 (1974).

Even if, contrary to proper procedure, *SEC* v. *Chenery*, 332 U.S. 194, 196 (1947); *Sec'y of Agriculture* v. *U.S.*, 347 U.S. 645, 653-4 (1954); *U. S.* v. *Chgo Milwaukee, St. Paul & Pac Ry.*, 294 U.S. 499, 510-511 (1935); *Angel* v. *Butz*, *supra*, this Court were to attempt its own analysis of label efficacy, it would find the administrative record barren of any expert comments, studies, surveys or treatises tending to establish that *ordinary* consumers would read the cautionary information contained in the challenged labels.[6] In

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[6] If the Department wishes to rely on agency "expertise or experience" to establish that consumers will universally read, understand and believe its cautionary labels, that reliance must "be clearly disclosed and adequately sustained", *SEC* v. *Chenery Corp.*, 318 U.S. 80, 94 (1943) "in the [challenged] order . . . itself", *Burlington Truck Lines* v. *U. S.*, 371 U.S. 156, 169 (1962), that is "in the 'Statement of the Bases and Considerations' filed with the adopted regulations." *Angel* v. *Butz*, 487 F.2d 260, 263 (10th Cir. 1973), *cert. denied*, 417 U.S. 967 (1974). No such disclosure appears in the present rulemaking. Indeed, there is complete silence with regard to the critical aspects about label reading, e.g., prior experience, specialized interest in product avoidance, consumer literacy, product appearance, etc., which, according to the testimony of Dr. Jacob Jacoby, world expert on consumer attention to safety instructions, are essential to any expert assessment of the likelihood that food product labels will or will not be read. Dr. Jacoby testified in support of the motion for preliminary injunction that the majority of conumers will not read, understand or believe the labels prescribed by the Rule. While his substantive conclusion is not to be considered by this Court, his testimony does show the inadequacy of the administrative record regarding expert analysis of label reading propensities of the broad spectrum of the consuming public.

fact, the rulemaker's thinking on this point was just the opposite: "not too many people read . . . handling instructions" but instead rely on "previous experience." App. 97-98. Yet previous consumer experience with hot dogs, lunch meats and bacon is that unrefrigerated use is safe. Their nitrite-free, counterpart look alikes authorized by the Rule are potentially lethal with the same handling.

It follows that even if the Rule were not vulnerable for "inadequacy of explanation", *National Nutritional Foods Assn* v. *Weinberger, supra,* regarding the efficacy of labeling, it should fall either for lack of rational support for any implied conclusion that labeling would suffice to protect the ordinary consumer under the look alike circumstances permitted by the Rule, *Burlington Truck Lines* v. *U.S.,* 371 U.S. 156 (1956), or for arbitrariness in exposing consumers to the risk of botulism in the face of the known inefficacy of cautionary labels.

The fact that the Rule requires the term "uncured" on the label of nitriteless meats supplies neither the missing analysis of labeling efficacy nor the rational support for the Rule demanded by *Overton.* Recognition of the need for distinguishing preserved from unpreserved products, App. 84-85, does not in itself rationally demonstrate that prefixing the term "uncured" to the traditional name will differentiate look alike products in the eyes of the ordinary consumer. Certainly the term will not warn those just mentioned who cannot or, relying on "previous experience", likely will not read the label. Nor will the administrative record support a finding that those who do read the term will "commonly" App. 85, understand it to mean no-nitrite. While it may be true, as indicated by the comments, that a few with special interest in the nitrite controversy will understand this term, it is, as the district court observed, irrational to conclude from this "that the 200 mil-

lion consumers in this country generally share the same definition." App. 32.[7] Certainly, the two comments relied on by counsel in the court below, Comments 55 and 238, do not provide the required record support for the critical conclusion that consumers universally understand the term "uncured" to mean "without nitrite."[8]

Likewise, recognition by the Department that consumers have safely handled uncured products such as bockwurst and bratwurst in the past does not supply the missing rational focus on the efficacy of labeling. *Contra* App. 12-13. These products do not *take on the appearance* of familiar preserved meats for, as the Department explained, their "basic color difference", Tr. 254-7, 260, distinguishes them. The challenged Rule, however, requires similarity in appearance and size as well as flavor and consistency, thus removing not only the color differential but also any size characteristics that might otherwise serve to distinguish cured from uncured.[9]

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[7] Petitioners daresay a poll by the court of its own members and staff regarding the meaning of the term "uncured" will not yield results significantly different from those of an informal survey reported by petitioners' expert at the hearing on the motion for preliminary injunction in which not one among some 250 college and graduate students and PhDs knew the meaning of this technical term. Tr. 122-3.

[8] The Department's complete silence as to the basis for its conclusion that "uncured" is "commonly" understood to mean nitrite-free does not come close to meeting the requisite "high standard of articulation." *Environmental Defense Fund* v. *EPA*, 465 F.2d 528, 541 (D.C. Cir. 1972).

[9] The court of appeals erroneously separated its analysis of petitioners' contentions regarding arbitrariness from the similarity requirements. See App. 10-13 and 16-19. The arbitrariness of the Rule arises precisely from the rulemaker's failure to consider the likely impact of the similarity requirements on the effectiveness of the prescribed labeling in preventing confusion and thereby botulism.

In sum, while the rulemaker facially considered[10] the question of labeling, his analysis, in clear violation of the standards set out in *Overton,* failed to consider, or to draw articulated, rationally drawn conclusions supported by record findings regarding the needs of the illiterate, the non-English speaking, those with impaired sight, those who have no interest in the nitrite-free meat controversy, and those exposed to the unpreserved product when the label is not attached or, in other words, the needs of most of us. That failing renders the rulemaking arbitrary.

b) Botulism risk

The inadequacy of the Department's inquiry regarding the increase of botulism poisoning in the absence of refrigerated handling is equally patent.

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[10] The supposed albeit undemonstrated efficacy of warning labels and lack of increased botulism risk would appear completely to be belied by a post-rulemaking official Department publication containing instruction for safe packing of a child's lunch of the unpreserved look alikes permitted under the Rule:

> "To pack a *safe* 'brown bag' lunch, use one of these methods: Prepare and freeze the meat sandwich the evening before . . . it will thaw in time for lunch. Pack sandwich in a small insulated container such as the commercially available foam plastic. Double wrap the sandwich and pack it with a cold piece of fruit or cold can of juice. Put a cold device into the lunchbag. The device might be a commercial freezer gel, a plastic bag filled with ice cubes, or a cleaned-out margarine tub that you have filled with water and frozen." Exh. 17; Tr. 151.

If deception, injury or confusion would be likely but for an unsupported general *assumption* that consumers will read explanatory information on a label, it is now common ground that the label cannot stand. *Houston* v. *St. Louis Independent Packing Co.,* 249 U.S. 479, 487 (1918); *Federation of Homemakers* v. *Butz,* 466 F.2d 462, 465-6 (D.C. Cir. 1972); *Cf. Federal Security Administrator* v. *Quaker Oats Co.,* 318 U.S. 218, 230 (1943).

The court of appeals held that the rulemaker adequately considered the dangers of botulism by noting in the proposal for rulemaking that reducing or eliminating nitrites "may better support" the production of botulism, App. 10, and by adopting the label requirements included in the final Rule. App. 11. The Department's assessment of increased risk, however, was premised entirely on the assumption that labeling would be completely effective in altering existing handling practices and assuring proper refrigeration:

> "This regulation is not expected to result in any increase in incidence of food poisoning from *Clostridium botulinum* toxin types of A & B, those primarily associated with red meats. Research has shown that spores of these types do *not generally grow at temperatures below 40° F.*" App. 80

The relevant factor, however, was whether an increased incidence rate was likely should uncured products be handled as their cured counterparts now are at 70°, 80° and 90°F for prolonged periods on picnics, kitchen tables and camping trips and in lunch pails and school lockers. The Rule's statement of bases and purpose simply does not address this point and nothing found in the court of appeals analysis fills the void.

The Department's disregard of this relevant factor is highly material for botulin is a killer toxin, Tr. 21, 101, and a finding, had it been made, of increased risk would, absent unfailing safeguards against unrefrigerated handling, if indeed such exist, render the Rule arbitrary on its face.[11] For the same reason, a finding of no increased

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[11] Even if some extraordinary reason were advanced (and none was) to justify tolerating a slight increase in risk, the rulemaker's quantification of the risk and basis therefor would still be highly relevant to judicial appraisal of the justification.

risk would require a demonstrably "reasoned decision", *Wellford* v. *Ruckelhaus*, 439 F2d 598, 601 (D.C. Cir. 1971) for "personal interests in life and health" are at stake and "close judicial scrutiny is particularly appropriate." *Id.* Yet no such reasoned analysis appears.[12] Given this

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[12] Admissions, made contemporaneously with the rulemaking by respondents and their agents (if this is what the Government meant below by "other" relevant material on which the rulemaker was entitled to rely), would cast doubt on the soundness of any downplay of the botulism risk if uncured product were exposed to handling now given some cured meats:

> "Consumers and food retailers handle cured meat products in ways that would foster the formation of the botulism toxin—for example, stores sometimes hold or display these products without refrigeration and consumers sometimes take them on camping trips or extended picnics. Without nitrite, *such practices*, particularly in combination, *could produce botulism in most people eating it.*" *FDA's and USDA's Action Regarding Nitrite*, Aug. 1978, Pl. Ex. 22, p. 28-29; Tr. 77
>
> "[W]ithout nitrites common usage of such products as hot dogs and ham would not be possible without *severe health hazards.*"
>
> "With current food processing and handling technology and practices, the protection provided by *nitrite is essential* to the public *health*. Its immediate *elimination* would subject the public to a *grave risk* of botulism." FDA/USDA Fact Sheet, March 28, 1979, Pl. Exh. 19, p. 1; Tr. 82.

[Petitioners note that the Rule would effect an "immediate elimination" of nitrite in the affected products]

> "Under current procedures for the manufacture or processing of food, and the conditions of its distribution and handling . . . [nitrites and nitrates] are essential to prevent the development in some meat food products . . . of a toxin that causes a deadly form of food poisoning known as botulism." Def. Bergland, et al., March 30, 1979, Pl. Exh. 20, p. 1; Tr. 80.

(footnote continued)

absence of requisite "clarity", *Phelps Dodge Corp* v. *NLRB*, 313 U.S. 177, 197 (1941) regarding botulism risk in the agency's stated basis of the Rule, this Court cannot elucidate "what the agency has left vague and indecisive",

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(footnote continued)

So would statements contained in the administrative record from the Department's Meat & Poultry Advisory Committee:

> "[T]here is no question . . . that the immediate elimination of nitrites from the food supply could create a *serious, acute public health hazard* in the form of botulism poisoning in some food products" (Grumbly, Adv. Tr. 21).
>
> "Without nitrites, you do have some special cautions in preservation (Nelson, Adv. Tr. 54).
>
> "Of course, a biggy was a concern for botulism and there were 30 comments that specified botulism directly, I mean, stated 'Botulism', in the comment, 'is a hazard if you proceed.'" (Nelson, Adv. Tr. 63).
>
> "[W]ithout nitrite, they [meat products] all can develop botulism without refrigeration" (Nelson, Adv. Tr. 63).
>
> "[T]here have been surveys made to determine the incidence of botulinal spores on meat products. I don't know of any way to determine that incidence except to have them grow. Now, it might be, you know, that they were able to grow them under very good conditions but, once they begin growing, it *doesn't take long for them to do what they have got to do*" (Nelson, Adv. C. Tr. 66-67).
>
> "[T]oxin can be produced at certain levels of temperature even though it would be under refrigeration for botulism" (Dr. May, Adv. Tr. 81-82).
>
> "[W]e are talking about something that literally can kill a person. It is not a slow process . . . It can actually kill you. It can do it very rapidly" (Dr. May, Adv. Tr. 101).
>
> "[T]here is plenty of information to show that, even at the lower levels [of spore load], you still get botulinal toxin produced, under the right conditions" (Def. Houston, Adv. Tr. 69).

SEC v. *Chenery*, 332 U. S. 194, 197 (1947) but must instead set the Rule aside. *U. S.* v. *Chicago Milwaukee, St. Paul & Pac. Ry.*, 294 U. S. 499, 510-511 (1935); *SEC* v. *Chenery*, 318 U.S. 80, 94-5 (1943).

II.

The Department Exceeded Its Authority By Promulgating the Rule For an Unlawful Purpose

The district court held that the Rule's purpose was the active promotion of markets for uncured products at the expense of producers of cured products, App. 36. The court of appeals held that the Department adopted the Rule to expand the availability of nitrite-free products. App. 15.[13] In either case the Department has exceeded its authority.

First, for reasons given, *supra* 18-22, the Rule's potential effect of increasing the incidence of botulism is not consistent with the public health and welfare, a consistency which the court of appeals held was required for the Rule's purpose to be valid. App. 14.

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[13] The court of appeals correctly held that the Rule was "*not based on* the asserted *cancer* dangers" of nitrite, App. 15, inasmuch as "not a word", *Rodway* v. *USDA*, 514 F2d 809, 814-815 (D.C. Cir. 1975), about cancer, potential carcinogencity of nitrite or related compounds, Department cancer policy, consumer concerns about the dangers of nitrites or relevant research appears in either the final Rule or its preamble. To hold otherwise would have placed the court in the position impermissibly of "substituting", *SEC* v. *Chenery*, *supra*, 332 U. S. at 196; *Cf. Tabor* v. *Joint Board*, *supra*, its own purpose for that of the agency and of sustaining a purpose as to which proper notice and opportunity to comment were not afforded. 5 U.S.C. § 553; *Rodway* v. *USDA*, *supra*, *Wagner Electric Corp.* v. *Volpe*, 466 F2d 1013 (3rd Cir. 1972).

Second, while a favorable competitive impact on one market segment may be justifiable as incidental and unavoidable in the accomplishment of some other congressionally authorized purpose, *Cf. Hiatt Grain and Feed, Inc. v. Bergland,* 602 F2d 929, 933 (10th Cir. 1979), *cert. denied,* ..... U.S. ..... (1980), the direct promotion, as here, of the interests of nitrite-free product manufacturers at the expense of competitors as an end in itself is outside the Department's statutory.

Finally, the means chosen by the Department to expand markets and/or consumer availability of nitrite-free products—namely the imposition of similarity requirements—are irrational. *Contra* App. 16-19. The court of appeals argues that these requirements are justified under the Department's general authority to establish standards of identity to prevent confusion and economic adulteration. App. 17. The obvious effect of the requirements, however, will, as the district court noted, be just the opposite:

> "Contrary to the purposes of the standards, the similarity requirements will confuse, if not deceive, consumers as to the identity of the products they are receiving and the handling requirements of those products." App. 39.

That confusion will not only be detrimental to expansion of the nitrite-free product market but will be disastrous to the market for nitrite-preserved products, especially in the event of a botulism fatality resulting from the confusion.

It is no answer to say without further analysis as did the court of appeals App. 17, that the authority for the present rulemaking falls within the Department's general ingredient or label approving power. No doubt that general authority exists. But it does not include the power to exercise such authority arbitrarily or irrationally.

III.

This Court Should Resolve the Conflict Between the Circuits Regarding the Requirements of the National Environmental Policy Act

The Second, Seventh and District of Columbia Circuits, among others, hold that the National Environmental Policy Act of 1969, 42 U.S.C. §4321 *et seq* (NEPA) and The Council on Environmental Quality, 40 C.F.R. 1500 *et seq,* require a rulemaker who determines not to file a draft and final environmental impact statement (EIS) to assess all relevant factors considered in that determination, state its reasons for not preparing an EIS, and affirmatively develop a reviewable administrative record in support of the decision not to file an EIS. *Trinity Episcopal School Corp* v. *Romney,* 523 F2d 88, 93 (2nd Cir. 1975); *Scientists Institute for Public Information* v. *Atomic Energy Commission,* 481 F2d 1079, 1094-5 (D.C. Cir. 1973); *Nucleus of Chgo. Homeowner Assn* v. *Lynn,* 524 F2d 225, 231 (7th Cir. 1975), *cert denied,* 426 U.S. 939 (1976); see 40 C.F.R. 1501.4(c) and (e) and 1508.13.

The present rulemaking, conceded by the Department to be of "major" character, App. 93, includes neither an EIS, consideration of factors (such as label reading practices of ordinary consumers) relevant to a decision not to file an EIS, reasons for not preparing an EIS, nor a developed record to justify not filing.

The Eighth Circuit excused this complete disregard of NEPA and in doing so is in direct conflict with other circuits, mentioned above, which construe NEPA to require setting aside rulemaking under such circumstances. The court of appeals does not deny that the Department disregarded NEPA but says instead that the court is able to sift out from the rulemaking record evidence of De-

partment attention to health dangers. App. 19-20. That, however, is in the manner of a forbidden post-hoc rationalization. *Citizens to Preserve Overton Park* v. *Volpe, supra,* 401 U. S. at 419-420; *FPC* v. *Texas,* 417 U. S. 380, 397 (1974); *Tabor* v. *Joint Board,* 566 F2d 705, 709-710 (D.C. Cir. 1977) and is not the court's function, *U. S.* v. *Chgo. Milwaukee, St. Paul & Pac. Ry., supra.* With NEPA, as with any other aspect of agency rulemaking, it is for the agency to state its grounds and the court merely to review them. "If those grounds are not "clearly disclosed", *SEC* v. *Chenery Corp., supra,* 318 U.S. at 94, the Rule cannot be sustained.

This Court should resolve the conflict in favor of the other circuits. In so resolving the conflict, this Court will assure the full analysis, "reasoned decision" and "balancing" of risks, *Karlen* v. *Harris,* 590 F2d 39, 44 (2nd Cir. 1978) commanded by Congress but absent here and thereby forestall substantial health hazards such as those created by the present rulemaking.[14]

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[14] The Final Impact Statement prepared by the Department, App. 72-82, is not equivalent to an EIS. App. 46; See 43 *Fed. Reg.* 21987 (May 22, 1978); *Cf.* 39 *Fed. Reg.* 18680 (May 29, 1974), CEQ Regulations 40 C.F.R. 1502.10 (1978); *Cf. Greene County Planning Board* v. *FPC,* 455 F2d 412 (2nd Cir.) *cert. denied,* 409 U.S. 849 (1972); *Steubing* v. *Brinegar,* 511 F2d 489 (2nd Cir. 1975); *S. W. Neighborhood Assembly* v. *Eckard,* 445 F. Supp. 1195 (D.D.C. 1978). Moreover, the FIS was markedly less sensitive to environmental effects significantly impacting the public health, *National Organization for Reform of Marijuana Laws* v. *U. S.,* 452 F. Supp. 1226 (D.D.C. 1978) and less exacting in its analysis than the duty under NEPA to file an EIS or to leave a visible explanation for not filing. *Scientists' Institute for Public Information, Inc.* v. *AEC, supra.*

CONCLUSION

Petitioners do not ask that this Court usurp the agency function or second guess well supported conclusions reached by the agency. Petitioners do not ask that this Court determine for itself whether the labeling system adopted by the agency will or will not be efficacious to prevent confusion under the look and name alike circumstances authorized by the Rule or whether the risk of botulism will be greatly or minimally increased in the event of such confusion. *Overton Park* and *Vermont Yankee* forbid such judicial intrusion.

Petitioners do, however, earnestly urge that this Court affirm the district court's strong conclusion that the rulemaker failed by a long measure adequately to examine the relevant factors of label efficacy and botulism risk, reach reasoned conclusions regarding them, and make and articulate findings based on the administrative record which lend credible support to those conclusions.

It may well be true that the administrative record will support a conclusion that members of an elite subgroup who read labels in exercising their personal preferences for additive-free food are not jeopardized by the Rule. But what is to happen to the rest of us? Petitioners believe Section 706(2)(A) was enacted by Congress to assure protection of the latter as well as the former and that this Court will not hesitate to provide Congressionally mandated review when as here agency rulemaking is arbitrary and capricious on its face.

WHEREFORE, Petitioners respectfully request that the writ issue.

Respectfully submitted,

DONALD P. COLLETON
JAMES L. FOX

Attorneys for Petitioners,
CHARLES GRASSLEY, THOMAS HAGEDORN,
NATIONAL PORK PRODUCERS COUNCIL,
and STEVEN SYMMS

Of Counsel:
ABRAMSON & FOX
One East Wacker Drive
Chicago, Illinois 60601
(312) 644-8500

APPENDIX

APPENDIX

UNITED STATES COURT OF APPEALS
For The Eighth Circuit

No. 80-1229

National Pork Producers Council, an Iowa corporation; Charles Grassley; Tom Hagedorn; and Steven Symms; and National Independent Meat Packers Association,

Appellees.

v.

Bob Bergland, Secretary of Agriculture; Carol Tucker Foreman, Assistant Secretary of Agriculture for Food and Consumer Services; and Donald Houston, Acting Administrator, Food Safety and Quality Service, United States Department of Agriculture,

Appellants.

Appeal from the United States District Court
for the Southern District of Iowa.

Submitted: June 13, 1980
Filed: September 23, 1980

Before HEANEY and BRIGHT, Circuit Judges, and HUNGATE, District Judge.*

HEANEY, Circuit Judge.

This appeal presents the question of whether the United States Department of Agriculture (USDA) properly exercised its authority when it issued regulations permitting

* The Honorable WILLIAM L. HUNGATE, United States District Judge, Eastern District of Missouri, sitting by designation.

nitrate and nitrite-free meat products to be sold under product names traditionally reserved for foods containing these compounds. The district court held that it did not. We reverse.

I

The history of nitrate and nitrite use in curing meat and poultry products is a long one. As early as Homer's time (900 B.C.), curing meat with salt was an established practice. Although it surely was not known at the time, the desert salts used in the curing process contained nitrate impurities, which caused cured meat to develop a characteristic spicy flavor and pink color. In addition, the curing process helped preserve the meat from bacterial spoilage. The cure was particularly effective, it is now known, in inhibiting the growth of *Clostridium botulinum*, the bacteria that produce the deadly toxin responsible for the food poisoning known as botulism.

Although curing is a centuries-old practice, it was not until the first part of the twentieth century that scientists identified the active agent responsible for the cure. The color, flavor and preservative effects were caused by the meat's reaction with nitric oxide, which was formed from nitrite, which was, in turn, formed from the nitrate used in the curing process. Because these reactions are difficult to control when meat products are cured with nitrate, the USDA formerly authorized the direct addition of nitrite in 1925. In some products, such as bacon, some form of nitrite is required by USDA regulations. *See* 9 C.F.R. § 318.7(b) (1980). Because nitrite was recognized as potentially toxic, however, a maximum residual amount of 200 parts per million was established. Nitrate was not directly regulated.

In the late 1960's, concern developed over nitrite use as studies suggested that nitrites combined with other compounds in the food or in the body to form nitrosamines,

which were known to be potent carcinogens in animals. As one report presented to a Senate Committee indicates, the possibility that nitrites could cause cancer touched off a flurry of activity:

> In October 1969, meat industry scientists met with the Assistant Secretary of Agriculture to discuss the possibility of a nitrosamine problem existing in U.S. cured meat products. In December of 1969, a group of USDA, FDA, and industry scientists met to discuss the problem, resulting in the scheduling of a cooperative research program to be funded by industry and actively participated in by industry, FDA, and the Department. The Food and Drug Administration (FDA) and the U.S. Department of Agriculture organized a scientific study group to review appropriate information and data. In 1971, the House Intergovernmental Relations Subcommittee conducted hearings on the issue of nitrosamine formation and the possible involvement of nitrite in cured foods. The matter was widely discussed by the public and the media, and further studies were carried out by the scientific community. Numerous conferences were held during 1972, to discuss available information on the role of nitrite in curing and preserving, and to determine what new information was needed.
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> * * * *
>
> Because of the widespread interest in the subject, the Secretary appointed an Expert Panel in 1973 to assess the data concerning the presence of nitrosamines in foods, to evaluate the public health significance and specific problems identified with the use of nitrites in foods, and to determine if alternate methods of processing were available.

Agriculture, Rural Development, and Related Agencies Appropriations for Fiscal Year 1979: Hearings before a Subcomm. of the Senate Comm. on Appropriations, 95th Cong., 2d Sess. 2936, 2937 (1978) (Final Report on Nitrites

and Nitrosamines to the Secretary of Agriculture by the Expert Panel on Nitrites and Nitrosamines).

One conclusion of the new round of studies was that nitrosamines are formed in nitrite-cured bacon when it is fried at high temperatures, particularly if it is cooked until crisp. As a result, in 1978, the USDA promulgated revised regulations that reduced the permissible levels of nitrite in bacon, required that other additives be used to lessen the likelihood that nitrosamines would form, and established procedures for testing bacon to ensure that it contains no confirmable levels of nitrosamines after cooking. 9 C.F.R. § 318.7(b) (1980); *see American Meat Inst.* v. *Bergland,* 459 F.Supp. 1308 (D. D.C. 1978).

Another, more tentative, conclusion of the scientific studies on nitrate and nitrite use was stated in 1978 by Paul Newberne of the Massachusetts Institute of Technology. The Newborne Report determined that nitrites themselves caused cancer in laboratory animals, even if nitrosamines had not formed prior to ingestion. This report prompted a wave of criticism from the meat industry on the one hand, and resulted in increased pressure on the USDA to completely ban the use of nitrites on the other. The Department resisted these pressures, however, finding that greater scientific study was required.[1] *See Schuck* v. *Butz,* 500 F.2d 810 (D.C. Cir. 1974).

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[1] Following the release of the 1978 Newberne Report, the FDA and the USDA established an Interagency Working Group on Nitrite Research to evaluate the MIT study. The interagency group, composed of scientists from the FDA, the USDA, the National Cancer Institute and the National Institute of Environmental Health Sciences, evaluated the design and conduct of the study and ordered an intensive pathology review of Dr. Newberne's diagnoses. In a report dated August 15, 1980, the group announced their findings, concluding that "insufficient evidence exists to support the

(footnote continued)

As the USDA and FDA studies continued, public awareness of the problem resulted in increased consumer demand for nitrate and nitrite-free products. USDA regulations, however, prohibited the production, sale or distribution of nitrate and nitrite-free products under their traditional names such as frankfurters, bacon, etc. As a result, consumers complained of some difficulty in identifying or finding the products they desired.

The Food Safety and Quality Service of the USDA responded to these complaints on April 28, 1978, by publishing a notice of proposed rulemaking in the *Federal Register*. 43 Fed.Reg. 18,193 (1978). In this notice, the USDA proposed to amend the federal meat inspection regulations to permit the sale of nitrate and nitrite-free products under their traditional names, provided that certain labeling and quality requirements were met.

In the sixty-day comment period following notice of the proposed rule, the USDA received 365 comments from individual consumers, consumer organizations, and industry and trade associations. In addition, the USDA consulted the National Advisory Committee on Meat and Poultry

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(footnote continued)

conclusion that sodium nitrite *per se* fed to rats causes cancer, based on the MIT study." The FDA and USDA announced in a news release accompanying the report that they have decided to contract with the National Academy of Sciences to review all relevant data on nitrite before additional action is taken. The agencies stated that the National Academy of Sciences "will conduct an independent assessment of all available scientific information about nitrite and will analyze scientific data and develop a research agenda on potential alternatives to nitrite as a preservative in meats and poultry." The release concluded: "Because of its widespread usage, we believe that our agencies must continue to be concerned about the effects, if any, that nitrite consumption might have on the public's health."

Inspection about the proposal and the comments. On June 14, 1979, the USDA issued a Final Impact Statement on the proposed rule, detailing the need for the rule, the options considered, and the expected impact of its implementation. On August 21, 1979, the USDA promulgated the final regulation, to be effective September 20, 1979. *See* 9 C.F.R. §§ 317.17(b) & (c), 318.7, 319.2.[2] The final rule provides that meat and meat products that are not cured with nitrates, nitrites or other preservatives may be sold under their traditional names, so long as the word "Uncured" appears on the label as part of the product name and the label states: "No Nitrate or Nitrite Added" and "Not Preserved—Keep Refrigerated Below 40° F. At All Times." In addition, the regulation requires that the uncured products be similar in size, flavor, consistency and general appearance to the products commonly prepared with nitrate or nitrite.[3]

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[2] 9 C.F.R. § 318.7, which prohibits the use of nitrates or nitrites in baby, junior or toddler foods, is not being challenged in this action.

[3] The final regulations in question read as follows:

§ 317.17. *Interpretation and statement of labeling policy for cured products; special labeling requirements concerning nitrate and nitrite.*

* * * *

(b) Any products, such as bacon and pepperoni, which is required to be labeled by a common or usual name or descriptive name in accordance with § 317.2(c)(1) and to which nitrate or nitrite is permitted or required to be added may be prepared without nitrate or nitrite and labeled with such common or usual name or descriptive name when immediately preceded with the term "Uncured" as part of the product name in the same size and style of lettering as the product name, provided that the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such

(footnote continued)

II

On September 20, 1979, the National Pork Producers Council, a trade organization representing approximately 92,500 United States pork producers, together with three members of the United States House of Representatives,

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(footnote continued)

product as commonly prepared with nitrate or nitrite, or both.

(c)(1) Products described in paragraph (b) of this section or § 319.2 of this subchapter, which contain no nitrate or nitrite shall bear the statement "No Nitrate or Nitrite Added." This statement shall be adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name.

(2) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall bear, adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name, the statement "Not Preserved—Keep Refrigerated Below 40° F. At All Times" unless they have been thermally processed to F° 3 or more; they have been fermented or pickled to pH or 4.6 or less; or they have been dried to a water activity of 0.92 or less.

(3) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall not be subject to the labeling requirements of paragraphs (b) and (c) of this section if they contain an amount of salt sufficient to achieve a brine concentration of 10 percent or more.

* * * *

§ 319.2 *Products and nitrates and nitrites.*

Any product such as frankfurters and corned beef, for which there is a standard in this part and to which nitrate or nitrite is permitted or required to be added, may be prepared without nitrate or nitrite and labeled with such standard name when immediately preceded with the term "Uncured" in the same size and style of lettering as the rest of such standard name: *Provided*, That the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate and nitrite: *And provided further*, That labeling for such product complies with the provisions of § 317.17(c) of this subchapter.

9 C.F.R. §§ 317.17, 319.2 (1980).

filed this lawsuit challenging the regulations. The National Independent Meat Packers Association, a trade association representing approximately 300 meat packers, was subsequently granted leave to intervene as a party plaintiff. The plaintiffs sought declaratory and injunctive relief.

On February 12, 1980, the district court entered a final order permanently enjoining the government from enforcing or applying the challenged regulations.[4] The court rested its decision on four grounds:

(1) The Secretary of Agriculture acted arbitrarily and capriciously because he failed to consider whether consumers would be subjected to botulism poisoning if they were to handle uncured products in the fashion in which they now handle cured products, and because there was no rational basis in the record for assuming that the required labels would effectively prevent confusion between the two types of products.

(2) The Secretary exceeded his authority under the Federal Meat Inspection Act, 21 U.S.C. § 601 *et seq.*, because the regulation was promulgated for the unlawful purpose of promoting or encouraging a market for nitrate and nitrite-free products.

(3) The Secretary exceeded his authority because the similarity requirement bore no rational relationship to the purposes of the Federal Meat Inspection Act and because it constituted a subjective standard of identity rather than an objective recipe or formula.

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[4] The district court had earlier denied a motion for a temporary restraining order, but had granted a motion for a preliminary injunction.

(4) The Secretary failed to comply with the requirements of the National Environmental Policy Act, 42 U.S.C. § 4321 *et seq.*, because he neither filed nor considered the need for an Environmental Impact Statement (EIS).[5]

III

Before discussing in detail the reasoning of the district court, we briefly consider the appropriate standard for reviewing regulations, such as these, promulgated pursuant to the "notice and comment" provision of the Administrative Procedure Act, 5 U.S.C. § 553(c). The standard "is that specified by 5 U.S.C. § 706(2)(A), which authorizes a reviewing court to set aside agency action found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Independent Meat Packers Ass'n* v. *Butz,* 526 F.2d 228, 238 (8th Cir. 1975), *cert. denied,* 424 U.S. 966 (1976). Furthermore, "unless an inadequate evidentiary development before the agency can be shown and supplemental information submitted by the agency does not provide an adequate basis for judicial review, the court * * * should limit its inquiry to the administrative record already in existence supplemented, if necessary, by affidavits, depositions, or other proof of an explanatory nature." *Id.* at 239. The district court explicitly recognized this standard in its opinion, but it nevertheless held a hearing that included the presentation of some evidence beyond "proof of an explanatory nature." We turn now to an independent examination of the record to determine whether the USDA acted arbitrarily, capriciously, or otherwise not in accordance with law.

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[5] In addition, the court rejected the plaintiffs' contention that the nitrate and nitrite-free products must be labeled "imitation" in accordance with 21 U.S.C. § 601(n)(3) finding that the uncured products were not imitations of their cured counterparts.

IV

A. *Arbitrary and capricious action.*

The district court's reasons for holding that the Secretary's action was arbitrary and capricious were that the USDA failed to consider whether consumers would be subjected to botulism poisoning if they were to handle uncured products in the same manner they now handle cured products and whether the labeling requirements would eliminate the risk. We find these rationales unconvincing.

First, it is clear from the record that the USDA was very concerned with the possible problem of botulism poisoning. The dangers of botulism and the handling practices necessary to ensure safety were carefully considered by the Secretary. As noted earlier, the USDA and other governmental agencies have been studying the health effects of nitrates and nitrites at least since the 1960's. These agencies have been looking for alternative preservatives and have sought ways to make nitrates and nitrites less dangerous without destroying their ability to control the growth of *Clostridium botulinum*. When the agency promulgated regulations to reduce the levels of nitrites in bacon, it reduced them only to the lowest level thought necessary to control these bacteria. More importantly, the agency expressly recognized the potential botulism danger in the official documents in this administrative proceeding. The notice of proposed rulemaking stated:

> The Administrator recognizes that meat products prepared without nitrate and/or nitrite or with reduced levels of nitrate and/or nitrite may better support the growth and toxin production of *Clostridium botulinum* that [sic] meat products prepared with the traditional levels of nitrate and/or nitrite currently permitted by regulation * * *. *Clostridium botulinum* intoxication (botulism) is a type of food poisoning which often causes death.

43 Fed.Reg. 18,193 (1978).

Similarly, the explanation accompanying the final rule reflected the agency's awareness of the dangers of botulism and the value of nitrites in reducing that danger. *See* 44 Fed.Reg. 48,959 (1979). Indeed, it was this awareness that prompted the strict labeling requirements in the regulations.

The agency was not only fully aware of the botulism risk, it considered evidence of the effect of the proposed regulation, particularly the labeling requirements, on that risk. It noted that some of the 365 comments submitted to it "expressed concern whether such labeling provisions would be adequate to protect against botulism with respect to * * * unpreserved products. In this connection, some commentators questioned whether products would always be handled in accordance with the warnings on the labeling and be kept below 40° F." 44 Fed.Reg. 48,959 (1979). Nevertheless, the agency found persuasive evidence that the benefits of the regulation would outweigh any potential safety problem. Many of the comments demonstrated consumer awareness of the potential dangerous consequences of marketing and consuming meat products that do not contain nitrates or nitrites.[6] Many commentators referred to the positive safe experiences they had had with purchasing uncured products in the past. Others stated that their knowledge of food products came from a careful reading of product labels. Still others indicated an understanding of the term "uncured" and expressed a willingness to adhere to the instructions on the label in exchange for an opportunity to buy meat products without nitrates or nitrites. Indeed, even the comment of the plaintiff-

[6] The public record also supports the proposition that consumers have become increasingly aware of the role of nitrates and nitrites in preserving meat products.

congresspersons in this action recognized the efficacy of warning labels; the congresspersons suggested, *inter alia*, that a revised regulation require strict warning labels.

Moreover, not only was the agency aware of the botulism danger at the outset, and not only did it consider further evidence of the danger, once it reviewed the evidence, it took positive steps to eliminate the chance of any danger resulting from the regulations. The final rule differed from the proposed rule in two significant respects. First, the labels on nitrate or nitrite-free products were required to contain the word "Uncured" as part of the product name. The agency described its reasons for the change as follows:

> [T]he Administrator has determined, based on the comments, that the use of nitrates and nitrites is of such importance in products preserved by these substances, that products prepared without such substances should have different names from those prepared with nitrates or nitrites in order to more clearly distinguish such products. Under these circumstances, it has been determined that such products prepared without nitrates or nitrites may bear the traditional name, but that the traditional name must be preceded by the term "Uncured."

44 Fed.Reg. 48,959 (1979).

Second, the proposed rule had permitted the sale, under traditional names, of products with low nitrate levels if they were labeled "Not Fully Preserved, Must Be Refrigerated Below 40° F. At All Times." This provision was deleted, partly in response to concern about whether "consumers might misuse such products not otherwise preserved, based on a false assurance that the listing of nitrates or nitrites in the ingredients statement would be understood to represent that products could be handled under the same circumstances acceptable for products fully preserved by nitrates or nitrites." *Id.* at 48,960.

These changes in the regulation are further proof that the agency carefully considered the evidence of botulism risk and made a reasoned determination in response to that evidence.[7]

After considering the submitted comments, consulting the Advisory Commission, and reviewing the relevant evidence before it, the agency made the following statement:

> The Administrator * * * is aware that products requiring such special handling such as pork sausage, bratwurst and bockwurst have presented no apparent health hazards even though prepared without nitrates or nitrites and marketed unfrozen. He concludes that consumers have demonstrated a knowledge of the handling practices necessary for any of such products prepared without nitrates or nitrites and that the prescribed labeling for such products, i.e., "Not Preserved—Keep Refrigerated Below 40° F. At All Times," will adequately inform the consumer of how to maintain such products in a wholesome condition until consumed.

Id.

Although the record contains some evidence that would suggest a different conclusion, we cannot say that the Secretary's determination is without basis in the record. Accordingly, the district court erred in holding that the Secretary acted arbitrarily and capriciously in promulgating these regulations.

B. *Unlawful purpose.*

The district court determined that the Secretary was without authority to promulgate the regulations in question because they were issued for the unlawful purpose

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[7] To further guard against any botulism risk, the USDA printed, primarily for distribution to consumers in supermarkets, educational pamphlets warning of the handling requirements of uncured products.

of promoting a market for uncured products. In support of this position, the district court quotes the Final Impact Statement released by the USDA on June 14, 1979, which states that one of the purposes of the regulations is "to allow the use of familiar names for the traditional, but nitrite-free processed meat products. Allowing these products to be marketed by traditional names will increase consumer awareness of their availability as well as consumption by those wishing to forego consumption of nitrite cured products." In addition, the court noted that the agency considered continuing the prohibition on the use of traditional product names on meat products without nitrates or nitrites, but rejected this option because "it does not facilitate the development of markets for nitrate and/or nitrite-free products." This, the court concluded, proves that the agency acted with an improper purpose.

We disagree. Congress expressly charged the USDA with "assuring that meat and meat food products distributed to [consumers] are wholesome, not adulterated, and properly marked, labeled, and packaged." 21 U.S.C. § 602. In our view, this directive authorizes the Department to ensure that the products desired by consumers be made available to them in a form and manner consistent with the public health and welfare. Every time the Secretary approves a product's ingredients or label, he, in one sense, is promoting that product. To be sure, the agency should not be promoting a particular company or a particular product of a particular company, but merely fulfilling consumer desires, while ensuring consumer health and safety, does not constitute such unlawful promotion.

The district court overlooked the agency's statement, both in the rulemaking notice and the explanation accompanying the final rule, that the regulations were proposed in response to requests by individual consumers, consumer interest groups and manufacturers. The comments sup-

port the agency's determination that nitrate and nitrite-free products were difficult to locate or not available to consumers. The regulation bears a rational relationship to this claimed purpose of availability.

Moreover, contrary to what the appellees would have us think, the producers of nitrate and nitrite-free preserved products have no right to be free from competition. *See Hiatt Grain & Feed, Inc.* v. *Bergland,* 602 F.2d 929, 933 (10th Cir. 1979), *cert. denied,* 62 L.Ed.2d 755 (1980). *See also Westport Taxi Serv., Inc.* v. *Adams,* 571 F.2d 697, 700 n.3 (2d Cir.), *cert. denied,* 439 U.S. 829 (1978). The challenged regulation is actually an exception to USDA regulations that formerly prohibited selling nitrate and nitrite-free products under their traditional names. The producers of nitrited products enjoyed a benefit from the old rule, but they have no vested right in the continuation of it. Upon the Secretary's finding that it was in the public interest to permit marketing under traditional names, the competitive effect on the producers of nitrate and nitrite-preserved products is of no consequence.

Finally, we emphasize the modest nature of the USDA proposal. Despite sustained pressure to ban the use of all nitrites,[8] the agency determined that regulations permit-

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[8] The district court stated that the public health threat from nitrite-induced cancer could not be considered as a valid purpose for the rule, because the USDA did not indicate in the final rules that the regulations' purpose was cancer prevention. We note that the failure to mention the alleged carcinogenic effects of nitrites was probably no accident. While the agency was studying the proposed rule, the United States Attorney General, in response to a USDA request, issued an opinion stating that if nitrites were found to be carcinogenic in animals, current law would require the USDA to ban their use in food products. *See* 43 Op. Att'y Gen. 1 (1979). Because scientific studies were not complete, the Secretary wisely decided to promulgate regulations not based on the asserted cancer dangers.

ting the sale of nitrate and nitrite-free products under traditional names would be sufficient to serve the public interest at this time. Under the new rules, no meat packer is required to manufacture nitrate and nitrite-free products, no wholesaler is required to supply them, and no retailer is required to stock them. Furthermore, the production and sale of nitrate and nitrite-preserved products are unaffected. In short, we conclude that the regulations are a rational response to the legitimate requests of concerned consumers and were not promulgated for an unlawful purpose.

C. *Similarity requirement.*

The district court's third rationale for invalidating the USDA regulations was that the requirement that uncured products be similar in size, flavor, consistency and general appearance to their cured counterparts was contrary to law. The court gave three reasons for this holding.

First, the court determined that "the similarity requirement is a standard of identity that bears no rational relationship to the purpose of such standards." In support of this assertion, the district court cited several cases purporting to define the purpose of the identity standards provisions of the Meat Inspection Act, 21 U.S.C. § 607(c). The court read these cases as holding that the purpose of such standards is to prevent the "economic adulteration" or to promote the "integrity" of meat food products. The similarity requirement in the challenged regulation does not serve this purpose, the court concluded, because it "will confuse, if not deceive, consumers as to the identity of the products they are receiving and the handling requirements of those products."

We cannot agree that the similarity requirement bears no rational relationship to the purposes of identity stan-

dards as intended by Congress. Initially, we note that none of the cases cited by the court involved successful challenges to USDA standards of identity. Most importantly, we think it clear that Congress intended the USDA to have the authority to issue the type of regulation here in question. Section 21 of the Act, 21 U.S.C. § 621, gives the agency broad authority to implement the statute: "[The] Secretary shall * * * make such rules and regulations as are necessary for the efficient execution of the provisions of this Act." Section 7(c) of the Act, 21 U.S.C. § 607(c), specifically provides that the Secretary may prescribe labeling requirements "to avoid false or misleading labeling" as well as definitions and standards of identity or composition "whenever he determines such action is necessary for the protection of the public." In our view, the similarity requirement is well within these powers granted the Secretary by Congress. It is designed to prevent the sale of products under traditional names when those products bear no resemblance to items commonly sold under those names. When a consumer buys a product labeled "Uncured Hot Dog," he will receive a product similar to any other "Hot Dog." Thus, the requirement furthers the goals of the Act by promoting truthful labeling.

The second reason given by the district court for holding the similarity requirement unlawful is that it "is a subjective standard of identity that is beyond the [USDA's] authority to promulgate or enforce." The court offers no authority for this proposition, however, other than to say that a standard of identity "normally sets forth a 'recipe' for a food." (quoting *American Frozen Food Inst.* v. *Mathews*, 413 F.Supp. 548, 554 (D. D.C. 1976), *aff'd on other grounds*, 555 F.2d 1059 (D.C. Cir. 1977)).

We find this reasoning unpersuasive. As noted earlier, the statutory grant of authority to the Secretary is broad, and no restrictions on the permissible types of standards are contained in the statute. The Secretary's implementation of the Act shows that subjective standards were contemplated; a number of current USDA regulations specify standards of identity that are not based on objective criteria. *See, e.g.*, 9 C.F.R. § 319.15(c) ("*Beef Patties*"—"Binders [and other ingredients may be added] only in amounts such that the product characteristics are essentially that of a meat pattie."); §§ 319.15(e) & 319.29 ("*Partially defatted beef fatty tissue*" & "*Partially defatted pork fatty tissue*"—"Such product shall have a pinkish color and a fresh odor and appearance"); § 319.80 ("*Barbecued Meats*"—must have "the usual characteristics of a barbecued article"); § 319.181 ("*Cheesefurters and similar products*"—"resemble frankfurters except that they contain sufficient cheese to give definite characteristics to the finished article."); § 319.700(a)(3)(iv) ("*Oleomargarine or margarine*"—may contain "[a]ny safe and suitable artificial flavoring substance that imparts to the food a flavor in semblance of butter."). The district court disregarded these regulations, noting that the Administrator of the USDA's Food Safety and Quality Service told the Advisory Committee that the Department did not regulate flavor and taste. This reliance on the comment of the Administrator is misplaced; the regulations speak for themselves. The court apparently was persuaded by the difficulty in enforcing subjective standards, and it may well be that the Administrator would wish to avoid such standards for that reason. Nevertheless, if the Secretary decides he is willing to assume the burden of enforcing this subjective standard of identity, it is not for us to say it would be too difficult.

The district court's final reason for invalidating the similarity requirement is that it "is so unorthodox and contrary to previous USDA policy and practice that it was incumbent upon defendants to give a reasoned explanation for their decision to impose the requirement." The soundness of this reasoning, obviously, is dependent upon the validity of the district court's finding that the USDA had not previously established subjective standards of identity for food products. For the reasons stated above, we are satisfied that the Secretary has set such standards in the past. Accordingly, the district court's third rationale for holding the similarity requirement invalid must fall.

D. *EIS requirement.*

Section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. § 4332(2)(C), provides in part that a federal agency must prepare a "detailed statement," commonly known as an EIS, whenever it proposes "major Federal actions significantly affecting the quality of the human environment." The district court held that the USDA did not fulfill the requirements of the Act when it promulgated the regulations involved in this case because it failed "to make a determination as to whether an EIS should have been prepared and [it failed] to develop a reviewable administrative record supporting a negative decision * * *."

We are not willing to find the regulations infirm on this basis. The EIS requirement of 42 U.S.C. § 4332(2)(C) is triggered when an agency proposes major federal action "significantly affecting the quality of the human environment." In this case, the record does not support a finding that such environmental effects may result from imple-

mentation of the regulations; moreover, it is clear that the agency considered the potential for such effects. The only "environmental" effects mentioned by the district court were the "significant public health concerns * * * implicated by the regulation." As detailed earlier in this opinion, however, the record shows that the USDA gave full consideration to the question of the regulations' health effects and determined that no significant health dangers were presented. Consequently, the sole ground for finding the existence of a major federal action "significantly affecting the quality of the human environment" is unsupported, and no EIS need be filed.

The decision of the district court is reversed.

A true copy.

Attest:

CLERK, U. S. COURT OF APPEALS,
EIGHTH CIRCUIT.

UNITED STATES DISTRICT COURT
For The
SOUTHERN DISTRICT OF IOWA—
CENTRAL DIVISION

NATIONAL PORK PRODUCERS COUNCIL, et al,
and
NATIONAL INDEPENDENT MEAT PACKERS ASSOCIATION,

vs.

BOB S. BERGLAND, et al

Civil Action File No. 79-431-C

JUDGMENT

This action came on for hearing before the Court, Honorable W. C. Stuart, United States District Judge, presiding, and the issues having been duly (heard) and a decision having been duly rendered,

It is Ordered and Adjudged that 9 C.F.R. §317.17 (b) and (c) and §319.2, 44 Fed. Reg. 48961 (August 21, 1979) hereby are declared to be arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law;

It IS FURTHER ORDERED AND ADJUDGED that defendants and their officers, agents, servants, employees, or successors and attorneys and those in active concert or participation with them are hereby permanently enjoined and restrained from enforcing or applying 9 C.F.R. § 317.17 (b) and (c) and § 319.2, 44 Fed. Reg. 48961 (August 21, 1979).

Dated at Des Moines, Iowa, this 12th day of February, 1980.

/s/ James R. Rosenbaum
Clerk of Court

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

NATIONAL PORK PRODUCERS COUNCIL, et al.,
Plaintiffs,

and

NATIONAL INDEPENDENT MEAT PACKERS ASSOCIATION,
Plaintiff-Intervenor,

vs.

BOB S. BERGLAND, et al.,
Defendants.

Civil No. 79-431-C

RULING AND ORDER

This is an action for judicial review of agency action pursuant to the Administrative Procedure Act (APA), 5 U.S.C. §§ 551, et seq. Plaintiffs are three members of the United States House of Representatives and two trade associations representing pork producers and meat packers. Defendants are the Secretary of Agriculture, the Assistant Secretary of Agriculture for Food and Consumer Services, and the Acting Administrator of the Food Safety and Quality Service (FSQS) of the United States Department of Agriculture (USDA). Plaintiffs seek a declaratory judgment that a USDA regulation permitting meat products prepared without nitrates or nitrites to be marketed under traditional names, such as bacon, ham, corned beef, and frankfurters, is arbitrary, capricious, an abuse of discretion and not otherwise in accordance with law.

They also request permanent injunctive relief preventing defendants from approving meat product labels under the challenged provision.

On April 28, 1978, the Administrator of FSQS proposed to amend the federal meat inspection regulations (See Federal Meat Inspection Act of 1907, 21 U.S.C. §§ 601 et seq.) to permit the preparation and sale of meat food products under those traditional names, even though such products, which have traditionally been cured with nitrates or nitrites, would be prepared without such preservatives. 43 Fed. Reg. 18193 (April 28, 1978). He further proposed that:

> (1) A product not prepared with nitrates or nitrites should be labeled 'No Nitrate or Nitrite Added —Not Preserved, Must Be Refrigerated Below 40° F. at All Times'; and
>
> (2) The preparation and sale of a product prepared without nitrate or nitrite should be permitted only if the product is prepared with some added substance or substances and is found by the Administrator to have a similar flavor and consistency to the product prepared with nitrate or nitrite.

Id. at 18194-95. Individual consumers, consumer organizations, trade associations and others submitted 365 comments to FSQS regarding the proposed amendments. FSQS reviewed the comments and on July 18, 1979, consulted the National Advisory Committee on Meat and Poultry Inspection (the Advisory Committee) with regard to the proposals and the comments thereon. On August 21, 1979, the Acting Administrator of FSQS (who is hereinafter referred to as the "Administrator"), promulgated a regulation permitting, inter alia, meat products prepared without nitrates or nitrites to be marketed under the traditional names of products prepared with nitrates or nitrites if:

(1) The traditional name on the label of the product prepared without nitrates or nitrites is preceded by the word 'Uncured' in the same size and style of lettering as the traditional name;

(2) The label carries the following information adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name:

(a) 'No Nitrate or Nitrite Added'; and

(b) 'Not Preserved—Keep Refrigerated Below 40°F. At All Times';

(3) The product is found by the Administrator to be similar in size, flavor, consistency and general appearance to the product commonly prepared with nitrate or nitrite.

44 Fed. Reg. 48959-961 (August 21, 1979).

On September 20, 1979, the National Pork Producers Council and Congressmen Grassley, Hagedorn and Symms filed this action. The National Independent Meat Packers Association was subsequently permitted to intervene as a party plaintiff. On November 9, 1979, plaintiffs' motion for a preliminary injunction came on for hearing before the Court. Subject to defendants' evidentiary objection noted infra and plaintiffs' request to present a consumer perception survey as evidence at a later date, it was agreed that the hearing would also constitute trial on the merits of plaintiffs' claims for a declaratory judgment and permanent injunction. See Fed. R. Civ. P. 65(a)(2). The Court did not rule on plaintiffs' request and would treat such application as a motion to reopen for newly discovered evidence. On November 14, 1979, the Court granted plaintiffs' motion for a preliminary injunction. Defendants have appealed therefrom, but the Court will file its ruling on the merits in order to provide defendants an opportunity to present the entire matter at one time.

Plaintiffs claim the regulation is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law", 5 U.S.C. § 706 (2)(A), on the following grounds, inter alia:

(1) Defendants failed to consider all relevant factors, including the danger that botulism, a deadly food poisoning, would develop in uncured products that are not properly refrigerated as well as the adequacy of the labeling requirements to prevent mishandling;

(2) The regulation was promulgated for the unlawful purpose of promoting a market for uncured products;

(3) The regulation's similarity requirement is an impermissably subjective standard of identity that

(a) bears no rational relationship to the purposes of standards of identity;

(b) was beyond defendants' authority to promulgate; and

(c) represents a radical but unexplained departure from previous standards of identity;

(4) The regulation requires uncured products to resemble cured products but does not require uncured products to be labeled as "imitation"; and

(5) Defendants did not prepare or consider preparing an Environmental Impact Statement (EIS).

Defendants contend that the Administrator acted reasonably and for a lawful purpose; that the similarity requirement is proper in all respects; and that neither the label "imitation" nor an EIS is required.

Defendants also insist that the Court's review of plaintiffs' claims on the merits is limited to the administrative

record.[1] Defendants rely upon Federal Power Comm'n. v. Trancontinental Pipe Line Corp., 423 U.S. 326, 331 (1976); Independent Meat Packers Ass'n v. Butz, 526 F. 2d 228, 239 (8th Cir. 1975), cert denied, 424 U.S. 966 (1976); Nickol v. United States, 501 F. 2d 1389 (10th Cir. 1974); and Wilson & Co. v. United States, 335 F. 2d 788, 799 (7th Cir. 1964), cert denied, 380 U.S. 951 (1965). Plaintiffs cite Hiatt Grain & Feed, Inc. v. Bergland, 446 F. Supp. 457, 467 (D. Kan. 1978), aff'd on other grounds, 602 F. 2d 929 (8th Cir. 1979), for the proposition that evidence outside the administrative record is admissible in order to assist the Court in understanding the technical, scientific and consumer perception issues presented; to assist the Court in determining whether an EIS should have been prepared; and to establish whether defendants have overlooked any relevant factors in promulgating the rule.

In a recent action for judicial review under 5 U.S.C. § 706(2)(A), the Eighth Circuit has held, on the basis of an extensive quotation from Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420-21 (1971), that:

> [U]nless an inadequate evidentiary development before the agency can be shown and supplemental information submitted by the agency does not provide an adequate basis for judicial review, the court in conducting the plenary review mandated by *Overton Park* should limit its inquiry to the administrative record already in existence supplemented, if necessary, by affidavits, depositions, or other proof of an explanatory nature.

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[1] In this case the administrative record consists of the proposed rulemaking, the Final Impact Statement (FIS) prepared June 14, 1979 by FSQS, the transcript of FSQS's consultation with the Advisory Committee, and the final rule and other information published August 21, 1979.

Independent Meat Packers Ass'n v. Butz, supra, at 239. In the instant case, the Court admitted evidence in support of an in opposition to plaintiffs' motion for a preliminary injunction. Its introduction for that limited purpose was not objected to. The Court admitted this same evidence on the merits of plaintiffs' claims for declaratory and permanent injunctive relief in order to permit the parties to make as complete a record as possible. In accordance with the principles set forth in Independent Meat Packers and Overton Park, supra, the Court has considered only the administrative record, supplemented by such explanatory evidence as is specifically noted hereinafter, in this ruling upon the merits of plaintiffs' claims. The evidence offered by the parties has not been considered for any other purpose.

SCOPE OF REVIEW

Under 5 U.S.C. § 706(2)(A), the Court is required to make a "thorough, probing, in-depth review" of the defendants' action. Overton Park, supra, at 415. If that scrutiny discloses that the defendants acted outside the scope of their authority, Schilling v. Rogers, 363 U.S. 666, 676-77 (1960); failed to consider "all relevant facts", Sabin v. Butz, 515 F. 2d 1061, 1069 (10th Cir. 1975); United States v. Nova Scotia Food Products Corp., 568 F. 2d 240, 251 (2nd Cir. 1977); failed to develop an adequate administrative record which supports necessary findings, WAIT Radio v. Federal Communications Comm'n, 418 F. 2d 1153, 1156 (D.C. Cir. 1969), cert. denied, 409 U.S. 1027 (1972); or failed to reach conclusions that are rationally supported by those findings, Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962); the administrative action will be deemed to be arbitrary, capricious, an abuse of discretion, and not in accordane with law and will be set aside. Hence, agency action will not be sustained if "in-

adequacy of explanation frustrates review". National Nutritional Foods Ass'n v. Weinberger, 512 F. 2d 688, 701 (2nd Cir.), cert. denied, 423 U.S. 827 (1975). See also United States v. Nova Scotia Food Products Corp., supra; Environmental Defense Fund, Inc. v. Ruckelhaus, 439 F. 2d 584 (D.C. Cir. 1971).

I.

Plaintiffs claim that since products preserved without nitrate or nitrite will have the name, appearance, taste and consistency of products preserved with nitrate or nitrite, consumers will be included to handle the unpreserved product in the way preserved products have been handled and thereby expose themselves to a greater risk of botulism. They contend that the labeling requirements will not alert the consumers of the unpreserved products of the danger to their health if those products are not properly refrigerated. Plaintiffs claim defendants acted arbitrarily and capriciously in issuing "a regulation which permits nitrite-free products to be sold under the disguise and name of nitrite-cured products such that consumers, unwarned of the switch, will handle the new product unsafely". In this connection, plaintiffs claim that defendants failed to consider (1) the potential for botulism if uncured products are treated in the same manner cured products have been treated, and (2) whether the required labeling will sufficiently alert the consumer to the differences in the safe handling characteristics of the two types of products.

Defendants claim that USDA considered all relevant factors, applied its experience and expertise, and made a reasonable judgment as to consumer behavior which should not be overturned by this Court. They contend that the labels are not misleading and that the Administrator had

a rational basis for his conclusion that the labels would adequately inform consumers of the nature and handling requirements of the unpreserved products.

Plaintiffs evidence at trial was primarily directed toward (1) whether consumers would read, understand and believe the labels on the unpreserved products, and (2) the likelihood that botulism would develop in unpreserved products not refrigerated in accordance with the instructions on the labels. The Court's task here is not to decide these issues but to determine whether defendants adequately considered them.

Upon the basis of the administrative record, the Court finds the regulation invalid for the reasons, inter alia, that there is no rational basis in the administrative record for the Administrator's conclusion that the information on the labels of the uncured products is adequate to prevent consumers from confusing the uncured products with the cured products, and defendants failed to consider the relevant factor of whether consumers handle cured products in a manner such that botulism would develop in uncured products handled in the same manner.

In the notice of the proposed rule, the Administrator recognized that meat products prepared without nitrates or nitrites "may better support the growth and toxin production of *Clostridium botulinum* [than] meat products prepared with the traditional levels of nitrate and/or nitrite currently permitted by regulation" and that "*Clostridium botulinum* intoxcation (botulism) is a type of food poisoning which often causes death." 43 Fed. Reg. 18193 (April 28, 1978). He concluded, and plaintiffs agree, that meat products prepared without nitrate or nitrite should be refrigerated at or below 40°F. at all times in order to be protected from botulism. *Id.* at 18194. The Administrator

also recognized the potential confusion among consumers between traditionally cured products and the products to be marketed under the proposed rule. He proposed the special labeling requirements for products prepared without nitrate or nitrite, "since meat products prepared with no nitrate or nitrite . . . could be confused with products containing the traditional levels of nitrate and/or nitrite." *Id.*

Numerous comments regarding the proposed rule suggested that consumers have developed established handling practices and uses for traditionally cured products whereby such products are not always refrigerated below 40°F. prior to preparation for consumption; that consumers would not read, understand or believe the proposed labels for the unpreserved products; that consumers would be confused or deceived by the similarity of the uncured products to the cured products; that consumers would handle the uncured products in the same fashion as cured products; and that botulism would develop in the uncured products as a result. See, e.g., Comments 253, 258, 260, and 280. Members of the Advisory Committee and defendant Foreman's own assistant expressed much the same concerns. See the Transcript of July 18, 1979, Consultation with the Advisory Committee, pages 70, 71, 76.

The Administrator noted that there was an issue as to whether cured products had been handled in a manner such that botulism would develop in uncured products handled in the same manner. *Id.* at 69-70. In the preamble to the final rule, he recognized the potential for confusion if cured and uncured products were marketed under the same name and the question whether the proposed labeling provisions would be adequate to protect against botulism in the unpreserved products. 44 Fed. Reg. 48959 (August 21, 1979). He concluded that the information on the final

label, with the addition of the term "uncured", would prevent botulism by informing consumers of the difference between the two types of products and the need to refrigerate the uncured products. Based on his awareness "that products requiring . . . special handling such as pork sausage, bratwurst and brockwurst have presented no apparent health hazards even though prepared without nitrates or nitrites and marketed unfrozen", *Id.* at 48960, he concluded

> that consumers have demonstrated a knowledge of the handling practices necessary for any of such products prepared without nitrates or nitrites and that the prescribed labeling for such products, i.e., 'Not Preserved-Keep Refrigerated Below 40°F. At all Times', will adequately inform the consumer of how to maintain such products in a wholesome condition until consumed.

Id. "In addition [to this information, he] determined, based on the comments, that the use of nitrates and nitrites is of such importance in products preserved by these substances, that products prepared without such substances should have different names from those prepared with nitrates or nitrites in order to more clearly distinguish such products." *Id.* at 48959. He concluded that the term "Uncured" would sufficiently distinguish such products because "[t]he term 'Uncured' in the labeling of a meat food product is commonly understood to mean that the product does not contain nitrates or nitrites, and that the product was not preserved with salt." *Id.*

The Administrator determined that the uncured products should be refrigerated below 40°F. in order to prevent the development of botulism. The comments suggested and defendants admit that traditionally cured products have not always been so handled. The Administrator

did not make any determination regarding the risk that botulism might develop in uncured products handled in the same manner cured products have been handled. Rather, he concluded that the uncured products would not be handled as cured products because the labels on the uncured products would distinguish them from the cured products and inform the consumer how to handle them properly. This conclusion was based upon his determination that the term "uncured" is commonly understood to mean "prepared without nitrates or nitrites" and his awareness that the marketing of other uncured products, such as pork sausage, bratwurst and brockwurst, has presented no health problem.

The term "uncured" is apparently understood by some to mean that a product is prepared without nitrates or nitrites. See Comments 83, 92, 122, 156, 157, 182, 192, and 238. The impetus for the rule change came from the producers of non-nitrite or nitrate preserved products and consumers who were concerned with the possible carcinogens in foods preserved by them. Similar non-nitrite products are available, but consumers claimed they have had difficulty locating them in the stores since they did not carry the traditional names. Many comments about the proposed rule change came from such consumers. To conclude, on the basis of the comments of persons interested in the controversy, that the 200 million consumers in this country generally share defendants' definition is irrational. Furthermore, unlike previously marketed uncured products, the uncured products permitted by defendants' regulation will be similar in size, appearance, taste and consistency to cured products. There is no rational basis in the administrative record for the conclusion that ordinary consumers, faced with a long-established product and a new product that differs only in the information on its label, will distinguish between the two products.

The Court agrees with defendants' argument that a fair respect for a statute that is primarily a regulation of labels requires rejection of an attack predicated on the notion that consumers are incapable of following instructions because of total illiteracy or universal disregard of instructions. See Stearns Electric Paste Co. v. Environmental Protection Agency, 461 F. 2d 293, 310 (7th Cir. 1972). See also Southern National Mfg. Co. v. Environmental Protection Agency, 470 F. 2d 194, 200 (8th Cir. 1972). However, it has long been recognized that few consumers read all of the information on labels and many cannot read labels at all. Houston v. St. Louis Independent Pkg. Co., 249 U.S. 479, 487 (1919). See also Federation of Homemakers v. Butz, 466 F. 2d 462, 466 (D.C. Cir. 1972). Indeed, the Secretary of Agriculture himself has argued that consumers do not read everything on a label and that even those who do might not understand all of the information thereon. Armour and Co. v. Freeman, 304 F. 2d 404, 413 (D.C. Cir.), cert. denied, 370 U.S. 920 (1962) (Prettyman, J., concurring). Recognition of these facts is not "a blow at the whole theory of labeling", as some might hold. See Id. Rather, it is an acknowledgment of "the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other." Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218, 230-31 (1943) (Footnote omitted).

The testimony of Mr. Fried, Acting Director of Products Standards and Labels, was not particularly helpful to defendants. He had no background to testify as an expert on consumer habits in reading labels or caring for nitrite preserved products. His primary reason for believing consumers would be protected was based on his experience that consumers put products displayed on shelves in the pantry and place products displayed in refrigerated cases

in the refrigerator. This is a pragmatic observation that is probably accurate, but it does not aid the defendants here because the nitrite preserved products are also sold from refrigerated cases. The Court feels strongly that the defendants failed to give adequate consideration to the dangers of botulism and to consumer conduct in reading labels and caring for nitrite products.

Although the Court would have felt more comfortable in reviewing the defendants' agency action if the public health arguments had been advanced by parties with a less direct economic interest in the outcome of this lawsuit, the Court is persuaded that the fears are genuine and that the USDA failed to give adequate attention to the dangers of botulism, the manner in which the public cares for nitrite preserved products and the effectiveness of labeling. The Court believes the USDA acted arbitrarily and capriciously in promulgating the questioned rule and in establishing the labeling standards.

II.

Plaintiffs claim that the regulation was promulgated for the unlawful purpose of promoting or encouraging a market for uncured products, thus favoring one class of producers over another. The FIS prepared June 14, 1979 states that the purpose of the final rule

> is to allow the use of familiar names for the traditional, but nitrite-free processed meat products. Allowing these products to be marketed by traditional names will increase consumer awareness of their availability as well as consumption by those wishing to forego consumption of nitrite cured products.

The FIS also states that defendants considered the alternative of taking no action with regard to uncured products but rejected that option "because it does not facilitate the

development of markets for nitrate and/or nitrite-free products".

Defendants do not claim that the purpose ascribed to the regulation by plaintiffs is a proper one. They deny that plaintiffs' statement of the purpose of the regulation is correct and claim that the regulation is designed to make available to consumers, who wish them, products that are similar to traditional products yet free of nitrates and nitrites, which are suspected but unproven carcinogens. Defendants claim that in adopting the final rule, the Administrator simply allowed the market to grow in response to consumer demand. The administrative record does not support this contention. Almost 170 uncured products were available on the market under their own names at the time the rule was adopted. To permit the use of the traditional names and to require similarity between cured and uncured products were not necessary to make the products available to those who wanted them. Therefore neither the use of the traditional names nor the similarity requirements bear a rational relationship to the claimed purpose of availability. As indicated earlier, those who wished to enjoy similar products without nitrate or nitrites instigated the rule change for their own convenience.

Defendants claim that "the final rule represents the effort of defendants to offer consumers the opportunity of obtaining pork products under their traditional names, . . . but without ingredients which many believe to be carcinogenic" and that they "acted reasonably . . . in balancing the public health . . . interests involved in this case." They imply that the purpose of the rule is to promote the public health by reducing the incidence of cancer in Americans. However, section 4(b) of the APA, 5 U.S.C. § 553(c), states that "the agency shall incorporate in the

rules adopted a concise general statement of their basis and purpose." Neither the proposed rule, the FIS, nor the final rule give any indication that such is the purpose of the final rule. Nor has research progressed to the point that the defendants could justifiably claim such purpose. Regardless of the alleged purpose, the nature and text of the questioned regulations clearly has the effect of increasing the marketability of uncured products. The Court can only conclude that approval of the use of traditional names and the similarity requirement in the final rule was given by the Administrator for the purpose of facilitating markets for uncured products, and thereby increasing the consumption of those products, at the expense of producers of cured products. Such purpose is not proper. This is not to say that, under proper labeling, uncured products that are similar to nitrite preserved products, are not welcome additions to the market place. However, it is not claimed and it cannot be held that the Federal Meat Inspection Act of 1907 (the Meat Act) allows the Administrator to take it upon himself to actively promote the marketing of a meat product. See 21 U.S.C. §§ 602, 607(c). See also Part III, infra.

III.

Plaintiffs claim that the regulation is contrary to the Meat Act, 21 U.S.C. §§ 601 et seq., because of the requirement that uncured products be found by the Administrator to be similar in size, flavor, consistency, and general appearance to cured products. They contend that this similarity requirement is a subjective standard of identity and that previous standards of identity or composition have always been objective recipes or formulas listing permissible or required ingredients and the percentages thereof in the product prescribed by the standard. They claim (1)

that the subjective nature of the similarity requirement represents a radical departure from previously promulgated standards and that defendants were therefore required to give a reasoned explanation for their departure from long-established administrative precedent; (2) that the purpose of standards of identity requires such standards to be based upon objective criteria, not subjective factors such as taste and general appearance; (3) that the similarity requirement bears no rational relationship to the purpose of standards of identity; and (4) that a subjective standard of identity is beyond defendants' authority.

Defendants contend that the similarity requirement is only a recent example of accepted, unchallenged USDA policy and practice. They argue that few of the 45 meat product standards promulgated by USDA could be characterized as mandatory recipes which specify mandatory ingredients in specific amounts. They also claim that USDA currently regulates factors such as general appearance and flavor on a regular basis. They point to 9 C.F.R. § 319.80 (1979), which requires barbecued meats to be so cooked as "to assume the usual characteristics of a barbecued article", and 9 C.F.R. § 319.181 (1979), which requires "cheesefurters" to "contain sufficient cheese to give definite characteristics to the finished article."

The Court believes that the similarity requirement is unlawful for three reasons. First, the similarity requirement is a standard of identity that bears no rational relationship to the purpose of such standards. Section 7(c) of the Meat Act, 21 U.S.C. § 607(c), authorizes the Secretary of Agriculture to prescribe standards of identity or composition for meat products "whenever he determines such action is necessary for the protection of the public." The precise

parameters of the Secretary's authority have not been defined by case law. However, the Court does not believe that the Secretary's authority is broad enough to validate the similarity requirement of the final rule.

The legislative history to the 1967 amendments to the Meat Act indicates that the Secretary's authority to issue standards of identity or composition under the Meat Act is based primarily upon Brougham v. Blanton Mfg. Co., 249 U.S. 495 (1919), and Houston v. St. Louis Independent Pkg. Co., 249 U.S. 479 (1919), two cases emphasizing the Secretary's power to prevent deceptive labeling and marketing of meat products by requiring adherence to what have come to be known as standards of identity or composition. S.Rep. No. 799, 90th Cong., 1st Sess. (1967), reprinted in 1967 U.S. Code Cong. & Ad. News 2198. In Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218 (1943), the Supreme Court indicated that the primary purpose of standards of identity promulgated under § 401 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 341, is

> to protect the consumer from 'economic adulteration,' by which less expensive ingredients were substituted or the proportion of more expensive ingredients diminished, so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold.

Id. at 230. In reliance upon Quaker Oats, the court in Armour and Co. v. Ball, 468 F. 2d 76 (6th Cir. 1972), cert. denied, 411 U.S. 981 (1973), concluded that one purpose of the Meat Act is "to empower the Secretary to adopt definitions and standards of identity or composition so that the 'integrity' of meat food products could be 'effectively maintained'." *Id.* at 81.

The similarity requirement in the regulation at issue here does not purport to further the purposes of standards of identity as stated in the cases outlined above. It will not prevent the "economic adulteration" or promote the "integrity" of meat food products. Contrary to the purposes of the standards, the similarity requirement will confuse, if not deceive, consumers as to the identity of the products they are receiving and the handling requirements of those products.

Second, the Court believes the requirement that uncured products be found by the Administrator to be similar in taste to cured products is a subjective standard of identity that is beyond defendants' authority to promulgate or enforce.[2]

A standard of identity "normally sets forth a 'recipe' for a food". American Frozen Food Institute v. Mathews, 413 F. Supp. 548, 554 (D.D.C. 1976) aff'd on other grounds, 555 F. 2d 1059 (D.C. Cir. 1977). "[I]t defines the composition of a food, prescribes mandatory as well as op-

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[2] Defendants contended during final argument that plaintiffs lack standing to raise any issue regarding the subjective nature of the taste requirement. No citation of authority or further explanation was offered. Apparently, defendants' argument is based upon the fact that plaintiffs were never denied approval of a label for an uncured product on the ground that the product was not found to be similar in taste to its cured counterpart. If such is defendants' contention, it is based upon an unduly narrow concept of standing in that its focus is upon a single issue rather than the entire case. Plaintiffs NPPC and NIMPA unquestionably have standing to challenge defendants' regulation. The validity and effect of the similarity requirement contained in 9 C.F.R. § 317.17(b) is the principal challenge to the regulation because it is the similarity requirement that plaintiffs allege will be the chief cause of consumer confusion, the danger of botulism, and the resulting economic loss to the association's members.

tional ingredients and establishes amounts or relative proportions of ingredients." *Id.* at 550. Many standards of identity for meat food products do not specify mandatory ingredients in specific quantities, yet they are nevertheless "recipes" based upon objective criteria. Although the "barbecued meats" and "cheesefurter" standards cited by defendants may appear to contain requirements as to how such products must taste, the Administrator stated to the Committee that USDA does not regulate flavor and taste. The reasons why USDA does not do so should be obvious. As disclosed at trial, a committee of three persons in USDA will make a subjective judgment as to the similarity of the uncured products to the cured products in approving the label. Compliance is monitored by an inspector in each plant. A standard that depends upon a subjective judgment as to taste would be impossible for USDA to apply in an even-handed manner. The product could vary with the subjective decision of each inspector. No objective guidelines could be established. The approval of the label of an uncured product would amount to an endorsement by USDA of the similarity of such product to its cured counterpart. The degree of confidence that a consumer could place in the integrity of an uncured product would, as plaintiffs contend, "depend quite literally on what the Administrator ate for breakfast".

Third, even if a subjective standard of identity were within the Administrator's power to prescribe, the requirement that uncured products be similar in taste to cured products is unlawful for another reason. As indicated above, similarity of taste has never been an element of a standard of identity. With few or no exceptions, standards of identity have been objective in nature. The requirement that uncured products taste like cured products is so unorthodox and contrary to previous USDA policy and practice that it was incumbent upon defendants to give

a reasoned explanation for their decision to impose the requirement. Their failure to do so necessitates remand of the regulation at a minimum. See Tabor v. Joint Board for Enrollment of Actuaries, 566 F. 2d 705, 711 (D.C. Cir. 1977); Greyhound Corp. v. Interstate Commerce Comm'n, 551 F. 2d 414, 416, 418 (D.C. Cir. 1977). See also Secretary of Agriculture v. United States, 347 U.S. 645, 653 (1954).

IV.

Plaintiffs also claim that the regulation is contrary to law because it requires the uncured products to imitate familiar cured products but fails to require the uncured products to bear the label "imitation" as required by 21 U.S.C. § 601(n)(3). They argue that the cured and uncured products differ in that the latter must contain added flavoring or coloring in order to resemble the cured products and also require refrigeration. They further contend that the addition of flavoring and coloring to the uncured products renders them inferior to the cured products. Plaintiffs claim that USDA has exceeded its authority in deviating from the statutory requirement that imitations be labeled as such. They rely upon Swift & Company v. Walkley, 369 F. Supp. 1198 (S.D. N.Y. 1973), wherein the court chastised USDA for approving the labeling of a product known as "All American Fun-Links" based not on a finding that it was not an imitation frankfurter, but rather upon acceptance of the view . . . that '[c]onsumers are reluctant to purchase products labelled "immitation" even though the products are very good and highly nutritious'." *Id.* at 1200. Plaintiffs claim that here, as in Walkley, USDA has disregarded the mandate of section 601(n)(3) because of its lack of confidence in the public's buying judgment. The Court does not believe plaintiffs' argument is applicable to these facts. The product at

issue in Walkley was found to be an imitation frankfurter; the uncured products at issue in the instant case are not imitations of their cured counter-parts, and to label them as such would be deceptive.

Title 21 U.S.C. § 601(n)(3) is a part of the Meat Act and states that a meat food product is "misbranded"

> if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word 'imitation' and immediately thereafter, the name of the food imitated . . . .

Whether one food product is an imitation of another depends of course upon the meaning to be given to the term "imitation". The Meat Act provides no definition. Defendants urge the Court to define an imitation food as a food which is "a substitute for and resembles another food but is nutritionally inferior to that food". The source of defendants' definition is 21 C.F.R. § 501.3(e)(1) (1979), formerly 21 C.F.R. § 1.8(e)(1)(1975), a regulation promulgated by the Food and Drug Administration (FDA) to define an imitation food subject to section 403(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) 21 U.S.C. § 343(c).

The FDA regulation and its definition of the term "imitation" were held to be reasonable and proper in Federation of Homemakers v. Schmidt, 539 F. 2d 740, 743-44 (D.C. Cir. 1976). The pertinent provisions of the FDCA and the Meat Act are similar in their express terms, and the purpose of each is to prevent misbranding. To apply here the definition espoused by defendants would appear to be reasonable at first blush. To do so would require the Court to hold that the uncured products need not be labeled imitation, because plaintiffs do not argue, and there is no basis for concluding, that the uncured products per-

mitted by USDA's regulation are in any way "nutritionally" inferior to cured products. However, USDA's failure to adopt FDA's definition by regulation, and the absence of any indication that such definition was actually applied by the Administrator in the instant case, lead the Court to believe that the definition to be applied here is not the one adopted by the FDA but rather the one developed by case law.

In 62 Cases of Jam v. United States, 340 U.S. 593 (1951), a case arising under section 403(c) of the FDCA, the Supreme Court stated that the meaning of the word "imitation" must be "left . . . to the understanding of ordinary English speech". *Id.* at 599. In United States v. 651 Cases, Etc., 114 F. Supp. 430 (N.D. N.Y. 1953), the court noted that "[t]he word [imitation] connotes inferiority . . . in the sense that [the product] is cheapened by the substitution of ingredients" and that "[r]esemblance alone is not enough to constitute imitation". *Id.* at 432 (citations omitted). Applying these standards to the instant case, the Court is convinced that the uncured products at issue need not and should not be labeled "imitation". Despite the fact that under the USDA's regulation, they must be similar in size, flavor, consistency and general appearance to the cured products, the nature of the differences between the cured and uncured products is not such that the latter would be commonly understood or said to be imitations of the former. The presence of added flavoring or coloring, as well as the special refrigeration requirements, might make the uncured products less desirable than the cured products in the minds of some. However, the presence of nitrates or nitrites in the cured products will make those products less desirable in the minds of others. Moreover, the substitution of flavoring and coloring for nitrates or nitrites cannot fairly be said to cheapen the

cured product or render the uncured product inferior. It is the failure to properly refrigerate an uncured product which will make it inferior. Improper handling of an uncured product will not make the product an imitation of a cured product but a dangerous food product that could not be approved under any label.

V.

Plaintiffs also claim that the rule was contrary to law because it has a high potential for significantly affecting the quality of the human environment in an adverse manner by making certain foods hazardous to the health of unwary consumers and an Environmental Impact Statement (EIS) should have been prepared as required by the National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321 et seq., and USDA's own policy on NEPA. See 39 Fed. Reg. 18678 (May 29, 1974). They claim USDA was at least required to assess all relevant factors (such as consumer label reading practices), state its reasons for not preparing an EIS, and develop a record supportive of its decision not to file an EIS. In response, defendants argue that no EIS is required because the regulation is not a "major" federal action and is not alleged to have a substantial effect on the "environment"; that the Court's review of the decision not to file an EIS is limited to a standard of reasonableness; and that the Final Impast Statement (FIS) prepared by USDA on June 14, 1979 shows that USDA properly exercised its discretion not to file an EIS. By way of reply, plaintiffs contend that the promulgation of the regulation was a "major" federal action significantly affecting the quality of the human "environment"; that the administrative record contains no reference to a decision to file or not file an EIS; and that defendants' failure to consider environmental factors,

make a decision whether to file an EIS, and develop a reviewable administrative record of such considerations and decision, is fatal to the regulation.[3]

The Court believes that the regulation at issue was promulgated contrary to law. Both the administrative record and the record made at trial are devoid of any indication that defendants made an express determination as to whether the preparation of an EIS was required. USDA's Policies and Directives, which state that "[e]ach USDA agency must use good judgment in determining when EIS's are required", indicate that a determination must be made. 39 Fed. Reg. 18678, 18679 (May 29, 1974). If a decision not to prepare an EIS is made, a statement of the reasons for that decision is required, Scientists' Institute for Public Information, Inc. v. Atomic Energy Comm'n, 481 F. 2d 1079, 1094-95 (D.C. Cir. 1973); and a reviewable administrative record supporting the decision must be developed. Nucleus of Chicago Homeowners Ass'n v. Lynn, 524 F. 2d 225; 231 (7th Cir. 1975), cert. denied, 424 U.S. 967 (1976). No such record was made here.

Defendants' arguments that an EIS was not required in this case are post hoc rationalizations for the failure

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[3] Plaintiffs also contend that the recently promulgated regulations of the Council on Environmental Quality (CEQ), as set forth in 40 C.F.R. §§ 1500.1 et seq. (1979), require the preparation of an EIS. Defendants have not responded to this contention. The CEQ regulations became effective on July 30, 1979, well over one year after defendants' publication of the notice of proposed rulemaking and less than one month prior to the publication of the final rule. Although the CEQ regulations were promulgated on November 29, 1978 and are to be applied to the fullest extent possible to activities ongoing at that time, see 40 C.F.R. § 1506.12 (1979), the parties have not argued the practicability of their application and the Court does not premise its decision in this case upon their applicability.

to consider the issue of preparation of an EIS, not reasons for a decision that an EIS was not required. USDA recognizes that its promulgation of a regulation is a federal action for NEPA purposes. 39 Fed. Reg. 18678, 18679 (May 29, 1974). "It is clear that NEPA was designed to cover almost every form of significant federal activity." Chelsea Neighborhood Ass'ns v. United States Postal Service, 516 F. 2d 378, 382 (2d Cir. 1975). USDA has stated that controversy is a factor in determining whether a federal action is "major". 39 Fed. Reg. 18678, 18679 (May 24, 1974). The promulgation of the regulation was not an insignificant government activity. The proposed rule generated 365 comments from a broad range of the public, and considerable public controversy. The adoption of the regulation was a major federal action. Furthermore, the possible occurrence of botulism as a result of consumer mishandling of uncured products is an "environmental" effect because significant public health concerns are implicated by the regulation. Cf. National Organization for the Reform of Marijuana Laws v. United States Department of State, 452 F. Supp. 1226 (D. D.C. 1978); Sierra Club v. Coleman, 405 F. Supp. 53, 55 (D. D.C. 1975), rev'd on other grounds sub nom. Sierra Club v. Adams, 578 F. 2d 389 (D.C. Cir. 1978). See also 40 C.F.R. §§ 1508.8(b), 1508.27(b)(2) (1979).

Defendants' argument that the FIS indicates that USDA properly exercised its discretion not to file an EIS is without merit. An FIS was never intended to take the place of an EIS, see 43 Fed. Reg. 21987 (May 22, 1978), and defendants do not contend that the FIS prepared on June 14, 1979 was prepared and circulated in accordance with 42 U.S.C. § 4332(2)(C). Even if the FIS could be considered to be an EIS, the conclusion stated in the FIS that the "regulation is not expected to result in any increase in incidence of food poisoning from *Clostridium*

botulinum'' would have to be rejected as arbitrary, capricious and unreasonable due to defendants' failure to consider all relevant facts in reaching that conclusion. See Part I, supra.

The Court does not hold that defendants were or are required to prepare an EIS. This question should be left to USDA in the first instance, subject to limited judicial review under the APA. See County of Trinity v. Andrus, 438 F. Supp. 1368, 1388 (E.D. Cal. 1977). The Court holds only that defendants' failure to make a determination as to whether an EIS should have been prepared and their failure to develop a reviewable administrative record supporting a negative decision were arbitrary, capricious, and unreasonable and invalidate the regulation.

IT IS THEREFORE ORDERED that 9 C.F.R. §317.-17(b) and (c) and § 319.2, 44 Fed. Reg. 48961 (August 21, 1979) hereby are declared to be arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law.

IT IS FURTHER ORDERED that defendants and their officers, agents, servants, employees, or successors and attorneys and those in active concert or participation with them are hereby permanently enjoined and restrained from enforcing or applying 9 C.F.R. § 317.17 (b) (c) and § 319.2, 44 Fed. Reg. 48961 (August 21, 1979).

Signed this 12th day of February, 1980.

/s/ *W. C. Stuart*

W. C. Stuart, Chief Judge
Southern District of Iowa.

5 U.S.C. § 553 provides in relevant part:

"(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subject issue involved.

* * *

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection."

5 U.S.C. § 706 provides in relevant part:

"To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

* * *

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

42 U.S.C. § 4332 provides in relevant part:

"The Congress authorizes and directs that, to the fullest extent possible: (1) the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in this chapter, and (2) all agencies of the Federal Government shall—

* * *

(C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on—

(i) the environmental impact of the proposed action;

(ii) any adverse environmental effects which cannot be avoided should the proposal be implemented;

(iii) alternatives to the proposed action,

(iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and

(v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Prior to making any detailed statement, the responsible Federal official shall consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved. Copies of such statement and the comments and views of the appropriate Federal, State, and local agencies, which are author-

ized to develop and enforce environmental standards, shall be made available to the President, the Council on Environmental Quality and to the public as provided by section 552 of Title 5, and shall accompany the proposal through the existing agency review process."

40 C.F.R. § 1501.4 provides:

"In determining whether to prepare an environmental impact statement the Federal agency shall:

(a) Determine under its procedures supplementing these regulations (described in § 1507.3) whether the proposal is one which:

(1) Normally requires an environmental impact statement, or

(2) Normally does not require either an environmental impact statement or an environmental assessment (categorical exclusion).

(b) If the proposed action is not covered by paragraph (a) of this section, prepare an evironmental assessement (§ 1508.9). The agency shall involve environmental agencies, applicants, and the public, to the extent practicable, in preparing assessments required by § 1508.9(a)(1).

(c) Based on the environmental assessment make its determination whether to prepare an environmental impact statement.

(d) Commerce the scoping process (§ 1501.7), if the agency will prepare an environmental impact statement.

(e) Prepare a finding of no significant impact (§ 1508.13), if the agency determines on the basis of the environmental assessment not to prepare a statement.

(1) The agency shall make the finding of no significant impact available to the effected public as specified in § 1506.6.

(2) In certain limited circumstances, which the agency may cover in its procedures under § 1507.3, the agency shall make the finding of no significant impact available for public review (including State and areawide clearinghouses) for 30 days before the agency makes its final determination whether to prepare an environmental impact statement and before the action may begin. The circumstances are:

(i) The proposed action is, or is closely similar to, one which normally requires the preparation of an environmental impact statement under the procedures adopted by the agency pursuant to § 1507.3, or

(ii) The nature of the proposed action is one without precedent."

40 C.F.R. § 1508.13 provides:

"'Finding of No Significant Impact' means a document by a Federal agency briefly presenting the reasons why an action, not otherwise excluded (§ 1508.4), will not have a significant effect on the human environment and for which an environmental impact statement therefor will not be prepared. It shall include the environmental assessment of a summary of it and shall note any other environmental documents related to it (§ 1501.7(a)(5)). If the assessment is included, the finding need not repeat any of the discussion in the assessment but may incorpo rate it by reference."

FEDERAL REGISTER, VOL. 43, NO. 83—
FRIDAY, APRIL 28, 1978

[3410-37]

Food Safety and Quality Service
[9 CFR Parts 317, 318, and 319]

NITRATE AND NITRITES

Federal Meat Inspection Regulations

AGENCY: Food Safety and Quality Service, USDA

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Federal meat inspection regulations to permit certain meat products which currently are preserved with nitrate and/or nitrite to be prepared either without these preservatives or with reduced levels of these preservatives and to permit them to be labeled and sold under the same name as that of the product when it is preserved with nitrite and/or nitrate. This document further proposes to prohibit the use of nitrate or nitrite in baby, junior, and toddler meat products. This action is taken in response to requests by consumer groups and manufacturers.

DATE: Comments must be received on or before June 27, 1978.

ADDRESS: Written comments to Hearing Clerk, U.S. Department of Agriculture, Room 1077, South Agriculture Building, Washington, D.C. 20250. See also comments under suppelmentary information.

FOR FURTHER INFORMATION CONTACT:

Mr. Irwin Fried, Acting Director, Product Labels and Standards Staff, Meat and Poultry Inspection Program, food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, 202-447-6042.

Comments

Interested persons are invited to submit comments concerning this proposal. Written comments must be sent in duplicate to the Hearing Clerk. Comments should bear reference to the date and page number of this issue of the Federal Register. All comments submitted pursuant to this notice will be made available for public inspection in the Office of the Hearing Clerk during regular hours of business.

Background Information

The Administrator has been requested by a number of consumer interest groups and by some manufacturers of meat products to permit the preparation and sale of cured meat products under traditional names such as bacon, corned beef, and frankfurters, when such products are prepared either without nitrate and/or nitrite or with reduced levels of nitrate and/or nitrite. The Administrator has determined that it is in the public interest to propose standards and labeling requirements for such products.

In order to assure that products labeled and sold under such traditional names as bacon or frankfurters but which are manufactured either without nitrate and/or nitrite or with reduced levels of nitrite and/or nitrate are of comparable flavor and consistency to cured meat products of the same name but prepared with traditional levels of nitrate or nitrite, the Administrator is proposing that traditional names may be applied to meat products prepared without nitrate and/or nitrite or with reduced levels of nitrate and/or nitrite only when the flavorings and other ingredients used in the preparation of such meat products will yield a meat product of similar flavor and consistency to that of the meat product when it is prepared with traditional levels of nitrate and/or nitrite.

The Administrator recognizes that meat products prepared without nitrate and/or nitrite or with reduced levels of nitrate and/or nitrite may better support the growth and toxin production of *Clostridium botulinum* that meat products prepared with the traditional levels of nitrate and/or nitrite currently permitted by regulation (shall result in no more than 200 ppm nitrite in the finished product). *Clostridium botulinum* intoxication (botulism) is a type of food poisoning which often causes death. Some question exists as to whether products prepared with less than 1,320 ppm nitrate or less than 120 ppm nitrite would be adequately protected against botulism unless such products were protected against botulism by some other means.

Based on agency experience and expertise, it appears that products would also be protected against botulism if held continuously under refrigeration at 40° F or below; preserved by thermal processing to F. 3 or more; preserved by fermentation or pickling to pH 4.6 or less; preserved by drying while 40° F or above 140° F to a water activity of 0.92 or less; or preserved by the addition of sufficient salt to achieve a brine concentration of 10 percent or more.

Also, customary marketing practices for fermented, semi-dry sausages are such that these products are frequently not kept refrigerated. Further, the addition of much more than 80 ppm nitrite would kill the bacteria starter cultures necessary for the fermentation of the product. However, it appears that such products would be protected against botulism if, in lieu of any of the methods specified above, they were preserved by the addition of at least 80 ppm nitrite coupled with fermentation to pH 5.0 or less and drying to a moisture-protein ratio of 3.1 or less to 1.

All products that are permitted currently by regulation to be cured by nitrate or nitrite, or both, but which require refrigeration to maintain wholesomeness are also required to bear on the label information concerning the need for refrigerated holding during storage at retail and in the home. However, since meat products prepared with no nitrate or nitrite or with reduced levels of these substances could be confused with products containing the traditional levels of nitrate and/or nitrite, special labeling requirements are being proposed for those meat products prepared without nitrate and/or nitrite or with reduced levels of nitrate and/or nitrite.

Under the circumstances referred to above, it is proposed that cured meat products which are not treated by one of the above named processes to protect against botulism, but which contain no added nitrate or nitrite, be labeled "No Nitrate or Nitrite Added—Not Preserved, Must Be Refrigerated Below 40° F at All Times." It is further proposed that meat products which are not preserved by one of the above named processes but which are prepared with less than 1,320 ppm nitrate and 120 ppm nitrite be labeled "Not Fully Preserved, Must Be Refrigerated Below 40° F at All Times." Such labeling would be in addition to all other mandatory labeling requirements.

Further, the Administrator proposes to prohibit the use of nitrate and nitrite in baby, junior, and toddler meat products. Currently, all baby, junior, and toddler meat products are prepared without the addition of nitrate or nitrite, or both, because their use has been voluntarily discontinued by industry. There is no need for their use as preservatives in these foods since these foods are thermally processed in hermetically sealed containers at temperatures and for time periods sufficient to destroy spoilage and food poisoning bacteria, including *Clostridium*

botulinum. Furthermore, it appears that babies, infants, and toddlers are less tolerant of nitrate and nitrite than adults, that there is no decided taste preference in babies, infants, and toddlers for nitrate or nitrite cured meats compared to those prepared without these preservatives, and that there is no useful purpose for their use in such foods.

Since it appears that nitrate and nitrite serve no useful purpose in baby, junior, or toddler meat foods, it is proposed that nitrate and nitrite be prohibited from use in such foods.

On the basis of the foregoing, it is proposed to amend the federal meat inspection regulations (9 CFR Parts 317, 318 and 319) as follows:

1. The table of contents for Part 317 of the regulations would be amended by reflecting the heading change for § 317.17 of the regulations set forth below; and §317.17 of the regulations (9 CFR 317.17) would be amended by designating the present text as paragraph (a), and by amending the heading and adding new paragraphs (b) and (c), to read as follows:

§ 317.17 Interpretation and statement of labelling policy for cured products; special labeling requirements concerning nitrate and nitrite.

* * * * *

(b)(1) Any products which is required to be labeled by a common or usual name or descriptive name in accordance with § 317.2(c)(1) of this part and which is permitted to be prepared with nitrate or nitrite, or both, as an ingredient, such as bacon or pepperoni, may be prepared without nitrate or nitrite and labeled with such common or usual name or descriptive name only if prepared with some

added substance or substances and found by the Administrator to have a similar flavor and consistency to such products preserved with nitrate or nitrite, or both.

(2) Any product which is required to be labeled by a common or usual name or a descriptive name in accordance with § 317.2(c)(1) of this part and which is permitted to be prepared with nitrate or nitrite, or both, as an ingredient, such as bacon or pepperoni, may be prepared with nitrate or nitrite, or both, but with less than 1,320 ppm nitrate and less than 120 ppm nitrite, and labeled with such common or usual name or descriptive name only if found by the Administrator to have a similar flavor and consistency to such product preserved with nitrate or nitrite, or both.

(c)(1) Product described in subsection (b)(1) of this secton shall bear adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name, the statement "No Nitrate or Nitrite Added —Not Preserved, Must Be Refrigerated Below 40° F at All Times," unless such product is preserved by thermal processing of to F_0 3 or more; fermentation or pickling to pH 4.6 or less; drying while below 40° F to a water activity of 0.92 or less; the addition of sufficient salt to achieve a brine concentration of 10 percent or more; or, in the case of fermented semidry sausage, the addition of at least 80 ppm nitrite coupled with fermentation to pH 5.0 or less and drying to a moisture-protein ration of 3.1 or less to 1.

(2) Product described in subsection (b)(2) of this section and section 319.2(b) of the subchapter shall bear adjacent to the product name in letters of easily readable style and at least one-half of the size of the product name the statement "Not Fully Preserved, Must Be Refrigerated Below 40° F at All Times," unless such product is

preserved by thermal processing at F_o 3 or more; fermentation or pickling to pH 4.6 or less; drying while below 40° F or above 140° F to a water activity of 0.92 or less; the addition of sufficient salt to achieve a brine concentration of 10 percent or more; or, in the case of fermented semi-dry sausage, the addition of at least 80 ppm nitrite coupled with fermentation to pH 5.0 or less, and drying to a moisture-protein ratio of 3.1 or less to 1.

§ 318.7 [Amended]

2. The term "Cured products" in the "products" column with respect to "Curing Agents" in the Chart in § 318.7(c)(4) would be amended in both places to read "Cured products, other than baby, junior, or toddler foods."

3. The table of contents for Subpart A of Part 319 of the regulations would be amended by adding "§ 319.2 Products and Nitrates and Nitrites," and a new § 319.2 would be added to Subpart A of Part 319 of the regulations to read as follows:

§ 319.2 Products and nitrate and nitrites.

(a) Any product for which there is a standard in this part, which permits or requires nitrate or nitrite, or both, as an ingredient, such as frankfurters and corned beef, may be prepared without nitrate or nitrite, and labeled with such standard name only if prepared with some added substance or substances and found by the Administrator to have a similar flavor and consistency to such product preserved with nitrate or nitrite, or both. Labeling for such product shall also comply with the provisions of § 317.17(c)(1) of this subchapter.

(b) Any product for which there is a standard in this part which permits or requires nitrate or nitrite, or both,

as an ingredient, such as frankfurters and corned beef, may be prepared with nitrate or nitrite, or both, but with less than 1,320 ppm nitrate and less than 120 ppm nitrite, and labeled with the standard name only if found by the Administrator to have a similar flavor and consistency to such product preserved with nitrate or nitrite, or both. Labeling for such product shall also comply with the provisions of § 317.17(a)(2) of this subchapter.

NOTE. — The Food Safety and Quality Service has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107.

Done at Washington, D.C., on April 25, 1978.

ROBERT ANGELOTTI,

Administrator,
Food Safety and Quality Service.

[FR Doc. 78-11608 Filed 4-27-78; 8:45 am]

NIMPA

The National Independent Meat Packers Association

734 15th Street, N.W. Washington, D.C. 20005

(202) 347-1000

June 27, 1978

Hearing Clerk
U. S. Department of Agriculture
Room 1007 South
Washington, D. C. 20250

Dear Sir:

The National Independent Meat Packers Association, known as NIMPA is a trade association composed of more than 300 member concerns, all engaged in the slaughter of livestock and/or the processing of meat food products. Most of the members of NIMPA operate establishments under federal inspection, and therefore have a strong interest in labeling requirements.

The Food Safety and Quality Service (FSQS) has proposed a rule (*Federal Register, Vol. 43, No. 83; April 28, 1978; pages 18193-18195*). NIMPA agrees with that portion of the proposed rule which would remove nitrite from infant and toddler foods. But the rule would allow meat products, heretofore made with sufficient levels of nitrite to cure the products, to be made with little or no nitrite. The rule would also allow these products to be labeled and sold under the same familiar name as the traditional, cured product. Additionally, FSQS would require that such meat products be of comparable flavor and consistency to cured meat products of the same name.

This proposed rule is apparently in response to concerns of some citizens and pressures from certain consumer groups about the use of nitrite as a

curing agent. In general, government response to citizen concern is laudable, but this particular action is reckless and dangerous.

Nitrite, even though currently the subject of much controversy and misunderstanding, nonetheless plays a most important role in our food supply. Hardly a space-age food additive, nitrite in various forms has been used for thousands of years as a curing agent. The single factor most responsible for this country's excellent safety record for meat products is the use of nitrite to cure meats. In addition to imparting a distinctive taste and color to meat and stabilizing it against spoilage, nitrite, and only nitrite, prevents botulism.

The very fact of the high degree of safety inherent in our meat products is the heart of the problem with FSQS's proposed rule. People know hot dogs are safe, even if they are taken on a picnic and perhaps not kept well chilled. People know bologna is safe to pack in a child's lunch and to be kept for hours in an unrefrigerated school locker. People know that if they mistakenly leave bacon on the kitchen counter long enough for it to come to near room temperature, they can still use it, re-refrigerate it, and use it again without risk. They know these things because they have learned them all their lives. They have learned they can confidently enjoy a wholesome diet of safe and reliable meat products.

To allow products with familiar names to be marketed without or with dangerously low levels of the one factor—nitrite—that has for so long rendered them so safe would be a very serious mistake. By the terms of the proposal itself, these new products would attempt to look like, taste like, and smell like their namesakes. Overall, we question the authority of the Administrator to decide whether non-cured meat products (no nitrite) have the same appear-

ance and flavor as the traditional products. These products would not, however, offer the same protection against food poisoning and spoilage.

The FSQS proposal would require that these new products have printed on the label "NO NITRATE OR NITRITE ADDED — NOT PRESERVED, MUST BE REFRIGERATED BELOW 40° F AT ALL TIMES" or, in the case of relatively low levels of nitrite, "NOT FULLY PRESERVED, MUST BE REFRIGERATED BELOW 40° F AT ALL TIMES." It is naive to think that this warning would remedy the situation. First, the illiterate, foreign speaking, or very young, who could not read the warning at all, would still recognize a product such as a hot dog, and treat it the way they have always treated hot dogs. Second, consumers who could read the warning often would not read it, and more often would not continuously recognize the serious consequences of treating a seemingly "familiar" product in a familiar way.

In today's real world of mass distribution and sales, perishable food necessarily must be able to withstand storage conditions which, while they should not occur, do subject such food to temperatures well outside the "safe" range. Packing house delivery trucks generally are properly refrigerated, but, invariably, some pallets of meat products may be left for periods of time on loading docks at warehouses or retail stores or in some temporary unrefrigerated storage areas. In warm weather, products encountering such conditions can temporarily reach temperatures conductive to the growth of harmful bacteria and conducive to spoilage. In retail stores, modern refrigerated display cases cannot consistently, reliably maintain temperatures below 40° F, particularly during hot weather when the cases are located near doors opening to the outside. When today's consumer purchases meat prod-

ucts, those products may or may not be taken directly home. Often, due to the consumer's long commuting time, or to being left in a hot car during an intermediate stop, the meat products may well be subjected to relatively high temperatures. Again, as with long-learned habits of handling cured meat products in the home, a warning label simply cannot be counted on to erradicate abuses which are an everyday occurrence. Nitrite provides the necessary margin of safety against such abuses.

Where the proposed rule deals with low nitrate products, and the labeling of those products, the problem becomes more complex, particularly since the rule attempts to deal with all classes of sausage and smoked meat products. We question the implied magical properties of the 120 ppm level for ignoring nitrite, particularly when there are no problems indicated with the currently allowed maximum of 156 ppm. We would point out that some semi-dry and dry sausage, as well as some other cured products, will not support the growth of Clostridium botulinum if preserved with 80 ppm nitrite or 120 ppm nitrite provided the remainder of the process is conducted properly. These products are shelf stable and should not be subjected to the "Must Be Refrigerated Below 40° F At All Times" labeling requirement. This would needlessly cause producers to change labels, would falsely cast suspicion on such products, and would confuse consumers who purchase those products.

Another major fault with the proposed regulation is that it has not been proven that traditionally cured product will be safe with little or no nitrite added, even if they are kept refrigerated. It may be possible, for instance, that certain products made with little or no nitrite may have to be kept frozen until the time of consumption. The necessary research has not been done, and the proposal should be withdrawn until it is done.

It is perfectly proper for a manufacturer to produce a meat product which is not cured and which needs constant refrigeration. Many such products are presently made. But to allow those products to be sold under the same name and to have taste, smell, and appearance imitating familiar, cured products is wrong. New and different products should have new and different names, so that all consumers will have no difficulty in recognizing them. It would be an unnecessary tragedy for illness or even death to demonstrate that long-learned habits of handling familiar foods are not suitable for uncured foods.

In view of the foregoing, and since there appears no scientific evidence to support the proposed rule, we urge the Department of Agriculture to withdraw the proposal.

Very truly yours,

John G. Mohay

John G. Mohay
President

JGM:jk

BEFORE THE
UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND QUALITY SERVICE
PROPOSAL TO ALLOW CERTAIN MEAT PRODUCTS PREPARED WITHOUT NITRATE AND/OR NITRITE TO BE LABELED AND SOLD UNDER THE SAME NAME AS THE PRODUCT WHICH IS PRESERVED WITH THESE SUBSTANCES
[Docket No. 78-11608]

COMMENTS OF
PACIFIC LEGAL FOUNDATION

RONALD A. ZUMBRUN
ROBERT K. BEST
RAYMOND M. MOMBOISSE
Pacific Legal Foundation
455 Capital Mall, Suite 465
Sacramento, California 95814
(916) 444-0154

ALBERT FERRI, JR.
DONALD C. SIMPSON
Pacific Legal Foundation
1990 M Street, N.W., Suite 550
Washington, D.C. 20036
(202) 466-2686

BY: *Donald C. Simpson*
DONALD C. SIMPSON

June 27, 1978

Pacific Legal Foundation (hereinafter "PLF") hereby submits its comments on the proposal by the United Sates Department of Agriculture, Food Safety and Quality Service (hereinafter "FSQS") to allow certain meat products currently preserved with nitrate and/or nitrite

to be prepared without these preservatives or with reduced levels and to permit them to be labeled and sold under the same name as that of the product when it is preserved with nitrate and/or nitrite. The proposed rule would also ban all use of nitrates and nitrites in baby, junior and toddler meat products. This proposal appears in the April 28, 1978 *Federal Register* (43 Fed. Reg. 18193-18195) and is proposed as an amendment to FSQS's "Federal Meat Inspection Regulations" (9 C.F.R. 317, 318 and 319).

For the purposes of simplification, and in view of the fact that nitrites are used more extensively than nitrates, "nitrite" will be used throughout this comment in place of "nitrate or nitrite."

Introduction

Nitrites are used in curing meats to protect against the formation of clostridium botulinum toxin in the meat products. This processing also gives the cured meat its distinctive flavor and texture. Proposed Section 317.17(b)(1) and (2) would allow a product to be produced with no nitrites or with reduced levels, and still be labeled by a common or usual name (see 9 C.F.R. 317.2(c)(1)) by adding substances to replicate the taste and consistency of the known product. The proposal would also require these products to bear the statement "No Nitrate or Nitrite Added — Not Preserved, Must Be Refrigerated Below 40° F. At All Times" or "Not Fully Preserved, Must Be Refrigerated Below 40° F. At All Times." 43 Fed. Reg. at 18194.

PLF questions the representation of such unpreserved products as traditional, accepted products on the ground that it is premature in the absence of adequate data on consumer use patterns.

A. *The Risk of Botulism*

The addition of nitrites to meat products protects against food-borne disease, especially the formation of botulinum toxin. Storage protection is also possible through refrigeration of the product at temperatures under 40° F.

Cured and processed meats have been sold without refrigeration, however, and are frequently exposed to ambient temperatures and open contamination. USDA, FSQS Subcommittee of the Expert Panel on Nitrites and Nitrosamines, *Preliminary Report: Economic, Environmental and Energy Impacts Associated With Alternatives to Nitrates and Nitrites In Processed Meats,* at 3 (1977). The average consumer is probably not aware that, without refrigeration, it is the nitrite which is guarding against botulism, and may assume that this same name product is equally protected against disease without needing to be refrigerated.

B. *The Warning Label*

The consumer who is accustomed to leaving the coldcuts or frankfurters exposed and is uncautious with leftovers is unlikely to change his or her habits when presented with what appears to be the same product, with the addition of a warning label.

The required duplication of the original product in color, form, and texture, coupled with the use of the same product name, will promote acceptance; the consumer's familiarity with the product, however, will reduce the likelihood that the label will be read for new requirements of product use.

Assuming the label is read, there is the added problem of consumer skepticism or indifference. Products which have been widely used and accepted have suddenly been

proclaimed "unsafe" and a rash of new warning labels have appeared. The result is that the labeling device is losing credibility, as is apparent with the cigarette and saccharin warnings. Where there is no apparent product change, the consumer may ignore any warnings or directions on new use or new dangers of products, assuming that they are merely new warnings attached to an old products which they *know* how to use.

C. *Consequences Of Allowing Both The Nitrite Cured Product And The Nitrite Free Product To Be Marketed Under The Same Name*

The proposed rule would allow both the product cured with nitrite and the product preserved without or with low levels of this substance to be available to consumers, and to be marketed under the self-same name. The potential for misuse and confusion seems obvious where consumers are confronted with two products which are virtually indistinguishable but demand different use habits.

The marketing of both meat products under the commonly-used name may increase the risk of botulism and other diseases. A higher incidence of botulism exists in countries which do not cure meats with nitrites. Council for Agricultural Science and Technology, *Rep. No. 74, Nitrite in Meat Curing,* at 17 (1978) (copy attached) (referring to studies of botulism authorities in France and Spain). Only the nitrite free products are available to consumers in these countries, however, necessitating only *one* pattern of use. The confusion resulting from two products with *different* use requirements but the same product name might even compound the botulism problem, with consumers being less cautious than where only a nitrite free product is available. In addition, the pack-

ing will become separated from the food product. As a result, leftovers and/or products stored out of their original packaging will give no warning of the procedures required to avoid risk. The effect of the proposed rule may therefore ultimately be a reduction in confidence and consumer use of *both* the nitrite free product *and* the nitrite cured product.

D. *False or Misleading Labeling*

The use of the traditional product name may constitute misbranding under the Meat Inspection Act, which provides "the term 'misbranded' shall apply . . . if its labeling is false or misleading in any particular." 21 U.S.C.A. § 601(n)(1). The customary conditions of product use must be analyzed in determining whether a label is indeed "false or misleading." A label indicating "Must Be Refrigerated Below 40° F at All Times" may itself be accurate. The consumer, however, has established general expectations of these cured meat products as currently marketed under specific product names. The nitrite free products, while tasting the same, perform differently from these expectations.

Conclusion

The realities of consumer behavior and the very real risk of botulism dictate reconsideration of the proposed rule. Simple warnings may not sufficiently change the consumer's established behavior patterns with known products.

PLF recommends that studies be conducted to determine the likely effects of implementation of this proposed rule on established consumer behavior, as well as the risk of botulism, before any further action is taken.

ECKRICH *We Make It Better For You*

PETER ECKRICH AND SONS, INC.

P.O. Box 388 — Fort Wayne, Indiana 46801

Phone (219) 481-2034

June 21, 1978

Hearing Clerk
U.S. Department of Agriculture
Room 1007, South Agriculture Building
Washington, D.C. 20250

Re: NITRATES AND NITRITES

Dear Sir:

Peter Eckrich and Sons, Inc. a major processor of sausage and luncheon meat specialists, submits the following comments on the proposed regulation concerning nitrates and nitrites as published in the Federal Register, Vol. 43, No. 83 — Friday, April 28, 1978.

The use of sodium nitrite at current levels has provided the consumer with relatively stable cured meat products with an excellent record of protection against botulism in commercial meat products for many years. While sodium nitrite gives substantial protection against rancidity, a chemical type of spoilage, it is undoubtedly most important as an essential factor in substantially decreasing the public health risk of botulism. Although the effect of sodium nitrite is not one that would guarantee absolute protection under every conceivable condition, at the levels used for many years in the real world, it has provided complete protection against botulism in the type of cured products considered here.

This proposal, if it became a rule, would be setting a trap for the consumer who might ignore or forget implications of a warning label due to long experience with the relatively high chemical and microbiological stability of traditional cured meat products, as well as the absence of fear due to the non-existent history of botulism in commercial cured meat products in the United States.

The essential concept of the proposed rule is that products either without nitrate and/or nitrite would be of comparable flavor and consistency to conventional cured meat products. This constitutes the basic consumer trap. If no nitrate and/or nitrite or reduced nitrate and/or nitrite products have the appearance, texture and flavor of conventional products without the botulinal protection associated with historically used level of nitrate and/or nitrite, we can only believe that what can happen, will happen. The use of traditional names only adds to the danger.

We feel so strongly that the proposed rule would subject American consumers to an intolerable risk that we do not choose to dilute the emphasis of our remarks by considering issues of lesser importance in our comments.

Sincerely yours,

H. Ned Draudt,

H. Ned Draudt, Ph.D.
Senior Research Scientist

HND/bjs

FINAL IMPACT STATEMENT

Date: June 14, 1979

Agency: USDA/FSQS

Contact: Dr. Houston

Phone: (202) 447-7025

1. *Title*: Nitrate and Nitrites

2. *Nature of Proposed Action and Groups Impacted*

This Food Safety and Quality Service regulation amends Federal meat inspection regulations (9 CFR Parts 317, 318 and 319) to permit certain processed meat products currently cured with nitrate and/or nitrite to be prepared without these agents and be labeled using traditional product names when preceded by the term "Uncured." This regulation only applies to processed red meat products. The statement "No Nitrate or Nitrite Added--Keep Refrigerated Below 40° F. At All Times" shall appear adjacent to the product name unless the produtc is preserved by thermal processing to F3 or more, fermentation or pickling to a pH of 4.6 or less, drying to a water activity (Aw) of 0.92 or less, or sufficient salt has been added to the product to achieve a brine concentration of 10 percent or more.

This regulation also prohibts the use of nitrate and/or nitrite in baby, junior, and toddler meat products.

This regulation will impact consumers and manufacturers of both processed meat products cured with nitrate and/or nitrite and similar processed meat products containing no nitrate and/or nitrite.

3. *Purpose and Need For The Action*

On April 28, 1978, a document was published in the FEDERAL REGISTER (43 FR 18193-18195) proposing to permit the preparation and sale of meat food products under traditional names, such as bacon, corned beef, and frankfurters, even though such products, which have been traditionally cured with nitrate and/or nitrite, would be prepared without, or with reduced levels of, nitrate and/or nitrite. The document also proposed to require certain cautionary information on the labeling of such products. Further, the document proposed to prohibit the use of nitrates or nitrites in baby, junior, and toddler foods.

A total of 365 public comments on this document were received by the issuing agency. These comments have been taken into consideration where appropriate and justified and the present action issued.

This action has two purposes. One is to allow the use of familiar names for the traditional, but nitrite-free processed meat products. Allowing these products to be marketed by traditional names will increase consumer awarness of their availability as well as consumption by those wishing to forego consumption of nitrite cured products. The second purpose is to reduce ingestion of nitrate and nitrite by infants and toddlers.

This action is needed because of the concern about nitrate and nitrite in food products. Recent research indicates nitrates and nitrites may be hazardous to human health. Nitrites in cured meat products, when cooked at high temperatures, can combine with secondary and tertiary amines to form nitrosamines. Tests with laboratory animals revealed these compounds can cause concern. More recent research suggests sodium nitrite itself can cause

cancer in laboratory animals. Partly as a result of these potential threats to health, many consumers have expressed a desire to reduce ingestion of nitrate and nitrite without having to give up consumption of the popular nitrite cured processed meat products.

The use of a traditional product name on a traditionally cured meat product currently requires the use of nitrate and/or nitrite in the product preparation. USDA Standards of Identity specify nitrite levels in curing solutions (not to exceed 120 ppm) for cured meat products. Labeling an uncured meat product under a traditional name constitutes "mislabeling." Hence, a "frankfurter" prepared without nitrate and/or nitrite must now be labeled "uncured cooked sausage."

Presently, there are approximately 34 establishments which market nitrate and/or nitrite-free processed meat products under 168 different product labels. The majority of these are sausage-type products. Since these products cannot be marketed under traditional product names, consumers are, in many cases, unaware of their existence or do not associate their current name with the traditional cured product. This information issue has slowed development of the market. This regulation will facilitate consumer choice by establishing the existence and availability of non-nitrite alternatives to traditionally cured meat products.

The industry has already discontinued use of nitrates and nitrites in baby, junior and toddler meat products using a thermal processing method with hermetically sealed containers. This process destroys the toxin producing organism, *Clostridium botulinum,* and spoilage bacteria.

4. *Options Considered.*

Option A—No Action.

This option would continue to prohibit the use of traditional product names on processed meat products without nitrate and/or nitrite. This option was rejected because it does not facilitate the development of markets for nitrate and/or nitrite-free products.

Option B—Requires Freezing.

Permit manufacturers to market processed meat products prepared without nitrate and/or nitrite under traditional product name when preceded by the term "UNCURED," and, require that these products be kept frozen at all times after production. This option was rejected because of the increase in production costs, particularly for energy.

Option C—Refrigeration and Labeling.

Permit manufacturers to market processed meat products prepared without nitrate and/or nitrite under traditional product names when preceded by the term "UNCURED," and, require that these products bear the statement "No Nitrate or Nitrite Added —Keep Refrigerated Below 40° F. At All Times" unless the product is preserved by one of the methods mentioned at the beginning of this impact statement. This is the option selected.

1) *USDA and Other Federal Costs.*

This regulation should not increase USDA or other Federal costs. The Meat and Poultry Standards and Labeling Division of FSQS will continue to be re-

sponsible for the review and approval of the existing 168 nitrite-free product labels and any new labels. Since the introduction of additional uncured products on the market is expected to be slow, no additoinal personnel, or budget needs are anticipated. This is based on meeting the current Division target label approval time of 48 hours per label.

Field inspectors of the Meat and Poultry Inspection Division, FSQS, will continue to review and monitor establishment processing procedures and product formulations to assure product safety and wholesomeness as a part of normal procedure. Current inspection program resources are considered adequate to fulfill the requirements of this regulation.

2) *Expected Impacts.*

on main purpose to which action is addressed and duration.

This regulation will facilitate the availability of nitrate and/or nitrite-free products in their traditional market forms. Consumers will have the option of selecting products which contain no nitrates and/or nitrites without giving up a wide range of familiar traditionally cured products.

The duration of this regulation is for an indefinite period or until amended further.

on non-Federal costs.

This regulation affects firms currently processing and marketing traditionally cured products containing no nitrate and/or nitrite, and those who manufacture baby, junior and toddler meat food products.

The firms wishing to use traditional names on their nitrate and/or nitrite-free products will be required

to comply with the label approval requirements of the law. The use of traditional names should be to their advantage, however, since products will become more readily recognized by retailers, wholesalers and consumers as nitrate and/or nitrite-free alternatives to traditionally cured meat products. It is estimated that redesign costs will average approximately $1,000 per label. Assuming all present processors of nitrite-free products will choose to use the traditional names, this totals $168,000 for the 168 products. Firms wishing to add nitrate and/or nitrite-free products to their line of cured products will incur the same average cost per product. There will be no appreciable effect on unit production costs.

The label redesign costs apply regardless of whether the freezing or refrigeration option is chosen. Assuming this regulation facilitates the development of markets for nitrate or nitrite-free products, other costs will be a function of the option chosen.

Processors electing refrigeration to preserve the new nitrate and/or nitrite-free products will have to make modest investments to determine appropriate product shelf lifes and inventory control systems. Firms may also need to modify voluntary open dating system for these products.

The freezing option would necessitate additional energy use and frozen storage capacity in plants producing and retail outlets selling such products. The costs of both are discussed below assuming a 45-day marketing-storage period is representative. The 45-day period reflects 10 days at the point of production and/or wholesale, 20 days at retail and 15 days in the home.

Freezing meat and marketing it in a frozen state is an energy intensive process requiring five times more energy than conventional chilling and refrigeration. The electrical energy differential between these two methods is approximately 87 kilowatt hours (Kwhr) per hundred pounds (cwt) of product. At 4.8 cents per Kwhr it costs about $4.18 more per cwt to market frozen product than it does to handle the same product under refrigerated conditions.

As processed cured-meat production is switched to uncured processed frozen meat, production costs could increase by 4.8 to 5.2 cents per pound of product. The lower figure would apply if current facilities are converted to freezing and the higher figure represents the construction of new facilities at both the processing and retail level.

Estimated Annual Costs Associated With Freezing Uncured Meat Products

Cost Elements	*Cost Impact (Millions)*	
	Low	*High*
Energy	$375.2	$375.2
Plant Freezer Construction	—	5.6
Plant Freezer Conversion	4.0	—
New Retail Freezers	—	89.7
Retail Cooler Conversion	48.5	—
Total	$427.7	$470.5
Addition to per pound costs:	4.8 cents	5.2 cents

The impact of the approximately 5 cents per pound increase in production costs on retail price will vary

with the cured product examined. For purposes of illustration, a higher priced cured product, salami, and a lower priced cured product, frankfurters, can be compared. Assuming the entire 5 cent increase is added to the retail price, salami would increase 2.5 per cent from 202.96¢/lb. to 207.96¢/lb. and frankfurters 3.7 percent (from 134.97¢/lb. to 139.97¢/lb.). This can be viewed as an approximate lower and upper bound of the impact on retail prices of cured products produced without nitrate and/or nitrite under the freezing option.

other significant economic impacts.

Whether the refrigeration or freezing option is selected there is no expected impact on employment, foreign trade, resource use, technology or productivity.

The refrigeration option is expected to increase competition within the industry due to the removal of the labeling barrier. Increased entry into this production area is expected to increase the supply of products containing no nitrates and/or nitrites.

The freezing option, however, would be expected to increase prices to consumers by approximately 5 cents per pound of product due to the increase in production costs. This latter increase is the result of increased energy use and greater required freezer storage capacity. The added freezer capacity will necessitate additional investment by the firm and a companion demand for credit.

other significant social effects.

No adverse impact from either the refrigeration or the freezing option is expected on safety, nutrition, communities, civil rights, institutions, invasion of privacy or other human concerns.

This regulation should increase the availability and consumption of nitrate/nitrite-free processed meat products and correspondingly reduce consumption of the traditionally cured meat products. A reduction in the ingestion of nitrate, nitrite or nitrosamines over time might result in a lower incidence of those types of human cancer caused by these chemical compounds. In economic terms, a lower incidence would provide several benefits: increased output and wages and smaller expenditures for medical care.

This regulation is not expected to result in any increase in incidence of food poisoning from *Clostridium botulinum* toxin types A and B, those primarily associated with the red meats. Research has shown that spores of these types do not generally grow at temperatures below 40° F. There is a small possibility that the refrigeration option might present a more immediate and continuous risk of a higher incidence of type E botulism food poisoning. This type can grow at temperatures as low as 4°c (38°F). Since commercial and home refrigeration units may not always be sufficiently low to prevent type E growth, a greater incidence of botulism with accompanying human and economic losses might occur.

Between 1972 and 1977 there were 92 outbreaks of botulism involving 221 persons. In 79 of the 92 outbreaks toxin type was identified. Type A was implicated in 49 outbreaks, type B in 20 outbreaks, type E in 12 outbreaks and type D in one outbreak.

distribution of effects.

Under both the refrigeration and freezing options larger firms will have advantages over smaller firms in product development and marketing. This gap would be much greater with the freezing option due to the capital requirements for freezer construction or conversion. Specialty firms producing only nitrate/nitrite-free products may have some difficulty in this area. Also under this option, the higher price nitrate/nitrite-free product will be more accessible, economically, to those consumers in higher income groups.

5. *Public Comment.*

The comment period extended from April 28, 1978, through June 28, 1978. A total of 365 responses was received from consumers, processors and various trade and consumer organizations. Many of the comments dealt with the potential health issues concerning botulism and cancer.

The remainder of the comments dealt specifically with the proposal. There were 110 comments received from consumers, all favoring the proposal. Comments from processors included six favoring the proposal and nine opposing it. Five organizations were in favor of the proposal and ten, primarily with producer and processor constituencies, opposed it. There were several comments received which supported the ban on the use of nitrate and nitrite in baby, junior, and toddler foods. There were no comments in opposition to such a ban.

The majority of the comments involved labeling of the products, health concerns, and handling practices. Some commenters indicated that the name for products cured with nitrates or nitrites should be distinguishable from the

name of such products prepared without nitrates or nitrites in order to avoid confusion between product names. Concern was also expressed whether 40°F was adequate protection for such products prepared without nitrate or nitrites, and that the product should be kept frozen. Others raised the possibility that abuses could occur because of improperly operating home refrigerators; careless food handlers; refrigerator breakdowns in storage facilities, transportation vehicles, and retail stores; and food taken on picnics, to work, and to school.

Approval: *Howard W. Hjort*

Director, Economics, Policy Analysis and Budget

Date 7-17-79

FOOD SAFETY AND QUALITY SERVICE

9 CFR Parts 317, 318, 319

Nitrates and Nitrites

Agency: Food Safety and Quality Service, USDA.

Action: Final rule.

Summary: This document amends the Federal meat inspection regulations to permit meat food products traditionally preserved with nitrates and/or nitrites to be prepared without nitrates or nitrites and be labeled and sold under the same name as that preserved with nitrates and/or nitrites, except that the term "Uncured" must precede such name and be part of the product name. Certain cautionary information would also be required to be included on the labeling of such products. Further, this document amends the regulations to prohibit the use of nitrates or nitrites in baby, junior, and toddler meat food products. These amendments are necessary to inform consumers of the nature of such products prepared without nitrates or nitrites, to insure that such products prepared without nitrates or nitries are safely handled, and to reflect the findings that nitrates and nitrites serve no useful purpose in baby, junior, and toddler meat food products.

Effective Date: September 20, 1979.

For Further Information Contact: Mr. Irwin Fried, Acting Director, Meat and Poultry Standards and Labeling Division, Compliance, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, [202] 447-6042.

Supplementary Information:

Background

On April 28, 1978, in response to petitions by consumer groups and manufactures, a document was published in the *Federal Register* (43 FR 18193-18195) proposing to permit the preparation and sale of meat food products under traditional names, such as bacon, corned beef, and frankfurters, even though such products, which have been traditionally cured with nitrite and/or nitrate, would be prepared without nitrite and/or nitrate or with reduced levels of nitrite and/or nitrate. The document also proposed to require certain cautionary information on the labeling of such products. Further, the document proposed to prohibit the use of nitrates or nitrites in baby, junior, and toddler foods.

Comments

Most of the 365 comments received were from individual consumers, industries, and organizations. The majority of the comments involved labeling of the products, health concerns, and handling practices. Comments postmarked after the June 28, 1978, closing date were not considered.

The proposal provided that any product having a common or usual name, descriptive name, or standard name and permitted or required to be prepared with nitrates or nitrites, or both, may be prepared without nitrates or nitrites and labeled with such name if prepared with some added substance or substances, and found by the Administrator to have a similar flavor and consistency to such product preserved with nitrates or nitries, or both.

Some commenters indicated that the name for products cured with nitrates or nitrites should be distinguished from the name of such products prepared without nitrates or

nitrites in order to avoid confusion between product names. The proposal distinguished these products which were not otherwise preserved by requiring the qualifying statement "No Nitrate or Nitrite Added" (in addition to the statement "Not Preserved, Must Be Refrigerated Below 40° At All Times") adjacent to the product name for those products prepared without nitrates or nitries and not preserved. The final rule requires all such products prepared without nitrates or nitrites to bear the qualifying statement "No Nitrate or Nitrite Added" in order to help inform consumers that these substances are absent from such products traditionally prepared with nitrates or nitrites. In addition, the Administrator has determined, based on the comments, that the use of nitrates and nitrites is of such importance in products preserved by these substances, that products prepared without such substances should have different names from those prepared with nitrates or nitrites in order to more clearly distinguish such products. Under these circumstances, it has been determined that such products prepared without nitrates or nitrites may bear the traditional name, but that the traditional name must be preceded by the term "Uncured."

The term "Uncured" in the labeling of a meat food product is commonly understood to mean that the product does not contain nitrates or nitrites, and that the product was not preserved with salt. Therefore although salt cured products were within the scope of that section of the proposal relating to the product name, they are not subject to this "Uncured" labeling requirement of the final rule. Accordingly, products cured with salt and prepared without nitrates or nitrites may bear common or usual names, descriptive names, or standard names, as appropriate.

The term "Uncured" would be required to be in the same size and style of lettering as the product named since it would be part of the product name.

It was also proposed to require such products prepared without nitrates or nitrites, to bear adjacent to the product name in letters of easily readable style at least one-half the size of the product name, the statement "Not Preserved, Must Be Refrigerated Below 40° F. At All Times" (in addition to the statement "No Nitrate or Nitrite Added") unless such products were preserved by one of the specified methods.

Many commenters, including 13 of the 14 members of the House Committee on Agriculture, expressed concern whether such labeling provisions would be adequate to protect against botulism with respect to those unpreserved products. In this connection, some commenters questioned whether products would always be handled in accordance with the warnings on the labeling and be kept below 40° F.

Some commenters indicated that abuses could occur because of improperly operating home refrigerators; careless food handlers; refrigerator breakdowns in storage facilities, transportation vehicles and retail stores; and food taken on picnics, to work, and to school.

A few commenters indicated that 40° F. was inadequate protection for such products prepared without nitrates or nitrites, and that the product should be kept frozen. On the other hand, a few commenters indicated the present practice of freezing "no nitrite added" products is unnecessary.

The Administrator has carefully considered these comments. He is aware that products requiring such special handling such as pork sausage, bratwurst and bockwurst have presented no apparent health hazards even though prepared without nitrates or nitrites and marketed unfrozen. He concludes that consumers have demonstrated a knowledge of the handling practices necessary for any of

such products prepared without nitrates or nitrites and that the prescribed labeling for such products, i.e., "Not Preserved Keep Refrigerated Below 40° F. At All Times," will adequately inform the consumer of how to maintain such products in a wholesome condition until consumed.

Some comments opposed the provisions relating to labeling products "Keep Refrigerated Below 40° F. At All Times" on the basis that the 40° F. requirement is too stringent because many refrigeration units used in stores and homes do not maintain a temperature of 40° F. or below. One comment indicated that stipulating that products should be "kept at 40° F." will increase costs 15 to 25 percent. The Administrator has determined that the "below 40° F." requirement should be retained as proposed. This temperature appears to be the normal operating temperature of most refregerating units and even with the known variability of such units products would be maintained in a wholesome condition during normal and usual shelf life.

It was also proposed that such products prepared without nitrates or nitrites be required to have similar flavor and consistency to those products preserved with nitrates or nitrites in order to be eligible for this special labeling. The purpose of these requirements was to be able to offer to consumers such products prepared without nitrates and nitrites with similar characteristics to those products preserved by nitrates or nitrites. In accordance with this purpose, the final rule also requires such products prepared without nitrates or nitrites to be similar in size and general appearance to such products prepared with nitrates or nitrites.

It was also proposed that such products prepared without nitrates or nitrites be required to be prepared with "some added substance or substances." This reference to

"some added substance or substances" was included as part of the criteria relating to whether such products would be similar in flavor or consistency. The important concept is that the product prepared without nitrates or nitrites be similar in flavor and consistency regardless of whether it contains "some added substance or substances." Accordingly, the reference to "some added substance or substances" has been deleted.

It was proposed to ban the use of nitrates or nitrites in baby, junior, and toddler foods. A small number of comments expressed support for a ban on the use of nitrates and nitrites in these foods. There were no comments in opposition to such a ban. The Administrator has decided to adopt the proposal to ban the use of nitrates and nitrites in these foods. Such a step is warranted since there is no need for nitrates and nitrites in these products for preservative purposes because they are thermally processed in hermetically sealed containers at temperatures and for time periods sufficient to destroy spoilage and food poisoning bacteria, including *Clostridium botulinum*. In addition, it appears that babies, infants, and toddlers are less tolerant of nitrate and nitries than adults. Further, nitrates and nitrites serve no useful purpose in baby, junior, and toddler meat food products.

The proposal contained provisions relating to products prepared with low levels of nitrates or nitrites. It was proposed that products prepared with less than 1320 ppm nitrates or 120 ppm nitrites (or less than 80 ppm nitrite coupled with additional requirements for fermented semi-dry sausage) be required to be labeled "Not Fully Preserved, Must Be Refrigerated Below 40° F. At All Times." unless preserved by one of the specified methods. Question has been raised as to whether, regardless of additional cauntionary language, consumers might misuse such prod-

ucts not otherwise preserved, based on a false assurance that the listing of nitrates or nitrites in the ingredients statement would be understood to represent that products could be handled under the same circumstances acceptable for products fully preserved by nitrates or nitrites. Further, with respect to the use of nitrates or nitrites in products at levels less than adequate for preservation, questions have been raised as to whether additional requirements should be implemented concerning the purposes for which these substances should be permitted to be used. These questions have not been fully resolved. Accordingly, provisions relating to low levels of nitrates and nitrites are not included in the final rule. However, consideration is being given concerning further rulemaking with respect to these matters.

Many of the comments expressed support for reducing the levels of nitrates and nitrites in meat food products or banning the use of these substances in all meat food products. Many other comments argued that nitrates and nitrites should not be banned generally from the meat food products. It was proposed to ban nitrates and nitrites in baby, junior, and toddler foods but the subject of a ban on the use of these substances in meat food products generally was not included in the proposal. Studies evaluating the safety and efficacy of nitrates and nitrites are currently underway or under consideration. Actions dealing with their use or disuse on a general basis will be the subject of other proceedings.

Other comments expressed concerns that in themselves are substantive but are not pertinent to the provisions of the proposal. Accordingly, these issues were not considered in connection with determinations relating to the final rule contained in this document. These comments included statements concerning the need for the Government to provide clean air and water, the proposition that Government is regulating too extensively, should reduce pay-

rolls, and stay out of the private sector's business; the economic consequences of removing bacon and other meat food products from the market; the use of salt (which is assumed to be sodium chloride) generally in products; the use of substitutes for nitrates and nitrites such as ascorbic acid or citric acid in meat food products; and cautionary statements on the labels of products containing nitrites.

One commenter indicated that shelf-life dates should be required on packages of products subject to this rulemaking proceeding. This is a general concept that relates to all meat food products and not just to the limited number of products affected by this rulemaking proceeding. The Administrator does view self-life dates as helpful labeling information and believes more processors should utilize shelf-life dates on a voluntary basis. Regulations concerning such voluntary dating are contained in § 317.8(b)(32) of the Federal meat inspection regulations (9 CFR 317.8 (b)(32)). Mandatory provisions relating to shelf-life dates were not part of the proposal, but are under separate consideration by the Department and could be the subject of a future rulemaking proceeding.

A few commenters questioned why the recommendations of the Expert Panel on Nitrites and Nitrosamines were not more closely adhered to. The Expert Panel's recommendations did not directly relate to the production and labeling of uncured products. Its primary recommendations related to a reduction in permitted levels of nitrite and nitrate in various products and to the need for further study concerning the use of nitrates and nitrites in products. These issues are currently being considered by the Department.

On July 18, 1979, the National Advisory Committee on Meat and Poultry Inspection was consulted regarding these

regulations. Members of the Committee expressed comments both in support of the proposal and in opposition to it. The Committee members did not raise issues outside the scope of the written comments as discussed above, but their views were also considered in the preparation of this final rule.

Editorial changes were made to clarify the language of §§ 317.17(b) and 319.2 and to amend the chart in §318.-7(c)(4) to specify the nitrates and nitrites are not permitted to be added to baby, junior, and toddler meat food products.

On the basis of the foregoing, the Federal meat inspection regulations (9 CFR Parts 317, 318 and 319) are amended as set forth below.

1. The table of contents for Part 317 of the regulations is amended to reflect the heading change for § 317.17 as set forth below; and § 317.17 is amended by changing the section heading, by designating the present text as paragraph (a), and by adding new paragraphs (b) and (c) as follows:

§317.17 *Interpretation and statement of labeling policy for cured products special labeling requirements concerning nitrate and nitrite.*

(a) • • •

(b) Any product, such as bacon and pepperoni, which is required to be labeled by a common or usual name or descriptive name in accordance with § 317.2(c)(1) and to which nitrate or nitrite is permitted or required to be added may be prepared without nitrate or nitrite and labeled with such common or usual name or descriptive name when immediately preceded with the term "Uncured" as part of the product name in the same size and style of

lettering as the product name, provided that the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate or nitrite, or both.

(c)(1) Products described in paragraph (b) of this section or § 319.2 of this subchapter, which contain no nitrate or nitrite shall bear the statement "No Nitrate or Nitrite Added." This statement shall be adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name.

(2) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall bear, adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name, the statement "Not Preserved—Keep Refrigerated Below 40° F. At All Times" unless they have been thermally processed to F$_0$ 3 or more; they have been fermented or pickeld to pH of 4.6 or less; or they have been dried to a water activity of 0.92 or less.

(3) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall not be subject to the labeling requirements of paragraphs (b) and (c) of this section if they contain an amount of salt sufficient to achieve a brine concentration of 10 percent or more.

§ 318.7 (Amended)

(2) The first reference to the term "Cured products" in the "Products" column with respect to "Curing agents" in the chart in § 318.7(c)(4) is amended to read "Cured products other than bacon. Nitrates may not be used in baby, junior, and toddler foods." The second reference to the term "Cured products" in the column is amended to read "Cured products. Nitrates may not be used in baby, junior, or toddler foods."

3. The table of contents for Subpart A of Part 319 of the regulations is amended by adding "§ 319.2 Products and nitrates and nitrites," and a new § 319.2 is added to read:

§ 319.2 *Products and nitrates and nitrites.*

Any product, such as frankfurters and corned beef, for which there is a standard in this part and to which nitrate or nitrite is permitted or required to be added, may be prepared without nitrate or nitrite and labeled with such standard name when immediately preceded with the term "Uncured" in the same size and style of lettering as the rest of such standard name: *Provided,* That the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate and nitrite: *And provided further,* That labeling for such product complies with the provisions of § 317.17(c) of this subchapter.

(Sec. 21, 34 Stat. 1264, as amended, 21 U.S.C. 621; 42 FR 35625, 35626, 35631)

Note.—This final rule has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations," and has been designated "significant." An approved Final Impact Statement is available from Mr. Irwin Fried, Acting Director, Meat and Poultry Standards and Labeling Division. Compliance, Food Safety and Quality Service, U.S. Department of Agriculture. Washington, D.C. 20250.

Done at Washington, D.C., on August 15, 1979.
Donald L. Houston,

Acting Administrator, Food Safety and Quality Service.

[FR Doc. 79-25824 Filed 8-20-79, 8:45 a.m.]
Billing Code 3410-DM-M

EXCERPTS FROM TRANSCRIPT of November 9, 1979 PROCEEDING

Page 141—

Mr. Fox: We would identify as Plaintiffs' Exhibit No. 28 a copy of an excerpt from the Federal Register dated August 21, 1979, which I will now show the witness.

Mr. Colleton: Pages 48959, 48960 and 48961.

Q. (By Mr. Fox) I ask you to examine the exhibit, Mr. Fried, and then answer my question. Where in that final rule is there consideration by the Department or the

[Page 142]

administrator of how consumers are to be protected if the label on these uncured products is removed, either in transit or in the home?

A. There is no statement, to the best of my knowledge, in this document that deals specifically with your question.

Q. Where in that final rule is there any consideration given as to how consumers are to be protected if the products, the uncured products, are sold, let's say, in bulk, as a consumer going into a delicatessen and buying a half-pound or pound of sliced bologna which the butcher or the delicatessen owner slices off in the machine, puts it together, wraps it up and gives it to the consumer?

A. There is nothing stated in this document that deals with that question.

Q. The same question as to selling such things as frankfurters or other uncured products in a meat market, not a self-service type, where the meats generally, and frankfurters and other items are displayed in the old fashioned cases with the butcher behind, and there are no labels on the product.

Where in the rule is there consideration given as to how the consumers are to be protected in that particular case?

A. There is nothing in this document that deals with your question.

[Page 143]

Q. Where in the final rule is there consideration given as to how non-English-speaking consumers are to be protected in their use—purchase, use and consumption of the non-nitrate products?

A. There is nothing in this document that deals with your question.

Q. Where in the final rule is there consideration of how functional illiterates among the consumer body are to be protected in the case of these non-nitrated products?

A. Again there is nothing in this document that deals with that question.

Mr. Hirt: Your Honor—Nothing, Your Honor. I'm sorry.

Q. (By Mr. Fox) Do you have any idea, as you sit here today, Mr. Fried, as to how many functional illiterates there may be in the United States?

A. No, I couldn't give that number.

Q. Would you think it would be a reasonable proportion, let's say in the neighborhood of what Dr. Jacoby referred to in his testimony?

A. I have absolutely no frame of reference to judeg that.

Q. You never made any investigation into that particular parameter?

A. No.

[Page 145]

Q. I show you what has been admitted in evidence as Plaintiffs' Exhibit 18, reading from Page 5 thereof—this

[Page 146]

happens to be a letter from Mrs. Foreman to Honorable Griffen Bell, the Attorney General of August 1978.

"It should further be noticed, however, that we have also been advised by such officials, namely, USDA and FDA administrative officials, that nitrites have been found to prevent the growth of clostridium botulinum, a natural contaminant of improperly preserved meat products, and which produces an extremely potent poison usually fatal to man; that there are no substances that could be ultilized under sufficiently broad scale to prevent botulism in commercially processed meats produced and without nitrites. Common usage of such products as hotdogs and ham would not be possible without severe health hazards."

Have you been familiar with that statement of the Department prior to the time that you came here today and sat on this witness stand?

A. Yes. I've got no objection to that statement.

Q. You were familiar with it?

A. Well, I'm roughly familiar with it, yes.

Q. And that statement is true; is that correct?

A. Yes. I have no problem with that statement at all.

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CROSS EXAMINATION

By Mr. Fox:

Q. I just have one question, Mr. Fried. Do you think consumers will understand what the word "uncured" means?

A. I think they will.

Q. Now, when I say "consumers", I mean everybody out there. Do you think they are going to understand what the word "uncured" means?

A. If you say everybody, and mean everybody, I would have to agree not everybody will.

Q. Do you think that the functional illiterates in the United States will understand what the word "uncured" means?

Mr. Hirt: Your Honor, I object.

Mr. Fox: Wait a minute. On what ground?

Mr. Hirt: I think this is an irrelevant issue in terms of functional illiterates because any label which FDA or USDA puts out is in standard English.

The Court: He may answer subject to the objection.

Q. (By Mr. Fox) Do you think the functional illiterates will understand what the word "uncured" means?

A. If they can't read it, I don't know whether they can understand it or not.

Q. Same thing—

A. If that's what you mean by "illiterate".

Q. The same thing would apply for non-English-speaking people.

[Page 193]

A. Yes, if they only see the English.

Q. The same thing might apply for a child who might pop a package of those franks into a grocery cart, going along shopping with his mother?

A. If the mother would allow him to do that, sure.

Q. Or a child sent to the store to buy a package of franks?

[Page 195]

Q. And what is the decision that the Department has made with regard to selling these particular products in bulk, or should the labels become obliterated or removed just as I removed the labels here before you this afternoon?

A. I believe I have answered a previous question as stating that it is my absolute belief that a person buying a product, it is in fact— I would agree with Dr. Jacoby. He said—I don't know about the figures, but he said not—as I recall, not too many peope read the handling instructions, and I believe that in many instances people buying—

and I believe this is because of previous experience, you buy a product in the refrigerated case, and you take it home and put it in the refrigerator. You don't put it on the kitchen table and leave it for three days and then eat it.

[Page 197]

Q. My question is, on what do you base your opinion that consumers would read those labels?

A. From everything that we have received in the Department, from people who want to have nitrite-free products.

Mr. Colleton: Thank you very much, Mr. Fried.

No. 80-742

FILED
JAN 16 19

In the Supreme Court of the United States

OCTOBER TERM, 1980

NATIONAL PORK PRODUCERS COUNCIL, ET AL., PETITIONERS

v.

ROBERT BERGLAND, SECRETARY OF AGRICULTURE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

WADE H. MCCREE, JR.
Solicitor General

ALICE DANIEL
Assistant Attorney General

ROBERT E. KOPP
AL J. DANIEL, JR.
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

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BRIEF FOR THE RESPONDENTS IN OPPOSITION

QUESTIONS PRESENTED

1. Whether the Secretary of Agriculture's rule for the labeling of nitrate-free and nitrite-free meat products is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," in violation of 5 U.S.C. 706(2)(A).

2. Whether the Secretary was required to prepare an environmental impact statement under the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*, prior to promulgating this rule.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-20) is reported at 631 F. 2d 1353. The opinion of the district court (Pet. App. 21-47) is reported at 484 F. Supp. 540.

JURISDICTION

The judgment of the court of appeals was entered on September 23, 1980. The petition for a writ of certiorari was filed on November 10, 1980. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Petitioners challenge a rule (9 C.F.R. 317.17(b), 317.17(c), 319.2) promulgated by the Secretary of Agriculture that permits nitrate-free and nitrite-free meat products to be sold under labels bearing traditional product names such as "frankfurters," "bacon," and "pepperoni," but only if the product name is preceded by the term "Uncured," printed in the same letter size and type as the name, and if, in addition, the label contains the following statement adjacent to the product name in letters at least one-half its size:

NO NITRATE OR NITRITE ADDED
NOT PRESERVED—KEEP REFRIGERATED
BELOW 40° F. AT ALL TIMES

(Pet. App. 91-92). Such products must also "be similar in size, flavor, consistency, and general appearance" to products prepared with nitrates or nitrites (*ibid.*).

1. Since the turn of the century, the Secretary of Agriculture has been required to protect this country's meat supply by careful and detailed regulation and inspection. The Federal Meat Inspection Act of March 4, 1907, ch. 2907, 34 Stat. 1260, authorized the Secretary to inspect all

cattle, sheep, swine and goats destined for interstate or foreign commerce, to direct that all such animals showing symptoms of disease be set apart and slaughtered separately, to conduct a post-mortem examination of the carcasses and parts of all such animals intended for human consumption, to label "inspected and passed" all carcasses and parts "found to be sound, healthful, wholesome, and fit for human food" (34 Stat. 1261), and to label "inspected and condemned" all carcasses and parts found to be otherwise (*ibid.*). The Act also prohibited the interstate sale or transportation of meat or meat food products not slaughtered and packaged in accordance with its provisions, and specified that such products could not be approved for sale unless they had "actually been inspected" and found, *inter alia*, "to contain no dyes, chemicals, preservatives, or ingredients which render such meat food product unsound, unhealthful, unwholesome, or unfit for human food * * *" (*id.* at 1264). The Act authorized the Secretary to specify permitted product trade names and to prohibit the use of names that are false or deceptive (*id.* at 1262). Finally, it directed him to "make such rules and regulations as are necessary for the efficient execution of the provisions of this Act" (*id.* at 1264).

In 1967, the Federal Meat Inspection Act was recast in its present form by the Wholesome Meat Act, Pub. L. No. 90-201, 81 Stat. 584. As thus amended and codified at 21 U.S.C. 601 *et seq.*, the Inspection Act prohibits the transportation, receipt and sale of any "adulterated" or "misbranded" meat or meat food product. 21 U.S.C. 606, 610. A product is deemed adulterated if, *inter alia*, it contains unsafe color or food additives or any other substance "which may render it injurious to health * * *." 21 U.S.C. 601(m)(1) and (2). A product is misbranded if, *inter alia*, its

packaging fails to disclose that it "contains any artificial flavoring, artificial coloring, or chemical preservative" (21 U.S.C. 601(n)(11)), or if it "fails to bear * * * such other information as the Secretary may require * * * to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition" (21 U.S.C. 601(n)(12)). The Act, as amended, continues to prohibit "false or misleading" labeling and to confer upon the Secretary authority to approve or disapprove trade names. 21 U.S.C. 607(d). Finally, "whenever he determines such action is necessary for the protection of the public [the Secretary] may prescribe: (1) the styles and sizes of type to be used with respect to material required to be incorporated in labeling to avoid false or misleading labeling * * *; [and] (2) definitions and standards of identity or composition for articles subject to this subchapter * * *." 21 U.S.C. 607(c). Required label information must be "prominently placed thereon with such conspicuousness * * * and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. 601(n)(6).

2. Nitrates and nitrites have long been added to meat products as color retainers and preservatives and have proved especially effective in retarding the growth of *Clostridium botulinum*, which are bacteria that produce a deadly toxin causing the food poisoning called botulism (Pet. App. 2). However, since the late 1960's concern increasingly has been voiced over the use of these additives in food because of growing evidence that they can combine with other ingredients in food or the body to form nitrosamines, agents shown to cause cancer in animals (*id.* at 2-3).

During the past decade, this problem was the subject of numerous meetings, conferences, and congressional hearings (Pet. App. 2-3). And in 1973, the Secretary of Agriculture appointed an Expert Panel on Nitrites and Nitrosamines to study the health problems involved and to consider alternative food processing methods (*ibid.*). See *Agriculture, Rural Development, and Related Agencies Appropriations for Fiscal Year 1979: Hearings Before a Subcomm. of the Senate Comm. on Appropriations*, 95th Cong., 2d Sess. 2936, 2937 (1978) (Final Report on Nitrites and Nitrosamines to the Secretary of Agriculture by the Expert Panel on Nitrites and Nitrosamines).

More recently, questions have been raised concerning whether nitrites are themselves carcinogenic, as distinct from the role they play, if any, in forming nitrosamines. A 1978 report by Paul Newberne of the Massachusetts Institute of Technology determined that nitrites do cause cancer in laboratory animals (Pet. App. 4). However, an interagency working group of scientists from the Food and Drug Administration, the Department of Agriculture, the National Cancer Institute, and the National Institute of Environmental Health Sciences concluded in August 1980 that there is " 'insufficient evidence * * * to support the conclusion that sodium nitrite *per se* fed to rats causes cancer, based on the MIT study' " (*id.* at 4-5 n. 1). At the same time, the agencies expressed continuing "concern[] about the effects, if any, that nitrite consumption might have on the public's health," and pledged to support further research (*ibid.*).[1]

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[1]The courts have upheld the Secretary's refusal to impose an immediate ban on the use of nitrates and nitrites in meat products (*Public Citizen* v. *Foreman*, No. 79-1690 (D.C. Cir. July 31, 1980); *Schuck* v. *Butz*, 500 F. 2d 810 (D.C. Cir. 1974)), and have also rejected efforts by the food industry to invalidate rules established in 1978 (43 Fed. Reg. 32136, 32137 (1978); 9 C.F.R. 318.7(b) (1979)) to reduce the level of nitrates and nitrites in bacon and to establish testing procedures to prevent the formation of nitrosamines during cooking (*American Meat Institute* v. *Bergland*, 459 F. Supp. 1308 (D.D.C. 1978)).

Eventually, public concern about the possible health hazards of nitrates and nitrites in meat products took the form of requests to the Department of Agriculture from consumers, consumer interest groups, and some meat manufacturers for a rule permitting the preparation and sale of nitrate-free and nitrite-free meat products under traditional product names (Pet. App. 5).[2] On April 28, 1978, the Secretary gave notice of a proposed rule that would permit this if certain protective labeling and other requirements were met (43 Fed. Reg. 18193; Pet. App. 52-59). In the Background Information section that accompanied the proposed rule, the Secretary discussed the desire of some persons and groups for traditional meat products free of nitrates and nitrites, the proposed requirement for similarity of flavor and consistency, and the effectiveness of nitrates and nitrites in protecting against botulism (Pet. App. 53-54). The Secretary also noted that "[b]ased on agency experience and expertise * * *," continuous refrigeration of meat products at 40° or below is also effective against botulism, as are various fermentation, drying, and pickling procedures (*id.* at 54).

On August 20, 1979, following the receipt of 365 comments including a two-page submission by petitioner National Pork Producers Council (Comment 291, A. 9-10),[3] the Secretary filed his final rule on nitrates and nitrites, effective September 20, 1979 (44 Fed. Reg. 48959-48961; Pet. App. 83-93). In his introductory "Comments" to the final rule, the Secretary addressed various specific concerns

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[2]USDA regulations then in effect prohibited the production, sale or distribution of nitrate-free and nitrite-free products under traditional names (Pet. App. 5).

[3]"A." refers to the joint appendix filed in the court of appeals.

raised by the statements received during the comment period (Pet. App. 84-91). In response to petitioner's concern about product confusion, the Secretary added to the final rule the requirement that products without nitrates or nitrites bear the term "Uncured" next to the product name (*id.* at 85). The Secretary addressed various other industry concerns as well.

3. On September 20, 1979, petitioners brought suit in the United States District Court for the Southern District of Iowa to enjoin the enforcement or application of the rule and to declare it "arbitrary, capricious, an abuse of discretion and not otherwise in accordance with law" (Pet. App. 22, 24).[4] They also claimed that the Secretary had failed to comply with the National Environmental Policy Act (*id.* at 44).

On February 12, 1980, following a trial on the merits, the district court concluded that "the USDA acted arbitrarily and capriciously in promulgating the questioned rule and in establishing the labeling standards" (Pet. App. 34), that the rule was promulgated for the improper "purpose of facilitating markets for uncured products, and thereby increasing the consumption of those products, at the expense of producers of cured products" (*id.* at 36), that the requirement that uncured meat products be similar to cured products, in size, flavor, consistency and general appearance is irrational and, insofar as flavor is concerned, "subjective"

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[4]The National Independent Meat Packers Association (NIMPA) was permitted to intervene as a party-plaintiff in the district court, filed a separate complaint, and participated fully there and in the court of appeals. By letter of November 11, 1980, its counsel advised the Clerk of this Court "that [NIMPA] has determined not to petition for a writ of certiorari * * * or otherwise participate * * *."

and "unorthodox" (Pet. App. 37-41), and that the USDA's "failure to make a determination as to whether an [environmental impact statement] should have been prepared and [its] failure to develop a reviewable administrative record supporting a negative decision were arbitrary, capricious, and unreasonable * * *" (*id.* at 47).

The court of appeals reversed (Pet. App. 1-20). After noting in passing that the district court had exceeded its authority by conducting an expansive evidentiary hearing (Pet. App. 9; see *Camp* v. *Pitts*, 411 U.S. 138 (1973); *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971)), the court of appeals determined (Pet. App. 10-13) that there was a reasonable basis in the administrative record for the Secretary's rule. The court observed (*id.* at 11):

> The agency was not only fully aware of the botulism risk, it considered evidence of the effect of the proposed regulation, particularly the labeling requirements, on that risk. It noted that some of the 365 comments submitted to it "expressed concern whether such labeling provisions would be adequate to protect against botulism with respect to * * * unpreserved products." * * * Nevertheless, the agency found persuasive evidence that the benefits of the regulation would outweigh any potential safety problem. Many of the comments demonstrated consumer awareness of the potential dangerous consequences of marketing and consuming meat products that do not contain nitrates or nitrites. Many commentators referred to the positive safe experiences they had had with purchasing uncured products in the past. Others stated that their

> knowledge of food products came from a careful reading of product labels. Still others indicated an understanding of the term "uncured" and expressed a willingness to adhere to the instructions on the label in exchange for an opportunity to buy meat products without nitrates or nitrites.

The court further noted that "not only was the agency aware of the botulism danger at the outset, and not only did it consider further evidence of the danger, once it reviewed the evidence, it took positive steps to eliminate the chance of any danger resulting from the regulations" (Pet. App. 12). Addressing petitioners' other arguments, the court of appeals held that the Secretary had considered possible environmental effects and had properly determined that no environmental impact statement was required (*id.* at 19-20), and "that the regulations are a rational response to the legitimate requests of concerned consumers and were not promulgated for an unlawful purpose" (*id.* at 16).

ARGUMENT

The decision of the court of appeals is correct, does not conflict with any decision of this Court or another circuit, and thus does not warrant further review.

1. The Secretary's labeling rule "is 'reasonably related to the purposes of the enabling legislation,' " is entitled to deference, and was properly sustained by the court of appeals. *Mourning* v. *Family Publications Service, Inc.*, 411 U.S. 356, 369 (1973) (citation omitted); accord, *Whirlpool Corp.* v. *Marshall*, 445 U.S. 1, 11-13 (1980); *Ford Motor Credit Co.* v. *Milhollin*, 444 U.S. 555, 559-560 (1980); *FCC* v. *National Citizens Comm. for Broadcasting*, 436 U.S. 775 (1978).

a. Petitioners seek to attract this Court's attention by their extravagant claim that the Department of Agriculture has "arbitrarily exposed the American consumer to the deadly hazards of botulism" (Pet. i).[5] The court of appeals squarely rejected this assertion, concluding that the Secretary was fully aware of and sensitive to the dangers of botulism and took adequate precautions to guard against it (Pet. App. 11, 12, 13).

Stripped of its rhetoric, petitioners argument that the rule is arbitrary and capricious (Pet. 12-18) hinges essentially on the contention that the Secretary failed to conduct a searching inquiry into the efficacy of precautionary labeling and that the court of appeals repeated the error. However, more than 70 years ago Congress made a legislative determination that labeling is an appropriate and effective means of protecting consumers of meat products and of informing them of the hazards associated with meat consumption. The Secretary is permitted, indeed required, to accept this legislative determination in fashioning appropriate labeling for

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[5]Proponents of the rule promulgated by the Secretary could have claimed with equal fervor that failure to adopt the rule would have arbitrarily exposed the American consumer to the deadly hazards of carcinogenic nitrosamines. Missing from the petition is an appreciation that the rule at issue was prompted by conflicting health concerns as grave as those on which petitioners focus. In upholding the Secretary's refusal to impose an immediate ban on the use of nitrates and nitrites as meat additives (see page 4 note 1, *supra*), the D.C. Circuit captured the Solomonic nature of the decisions the Secretary is called upon to make (*Public Citizen* v. *Foreman*, No. 79-1690 (July 31, 1980), slip op. 16):

> The use of nitrites in curing bacon presents difficult medical and scientific questions. Some believe the use of nitrites causes cancer while others claim nitrites are needed to prevent botulism. Such questions go beyond our competence, and we must defer to the administrative agencies with their technical expertise on these matters. We find that the USDA in its regulation of nitrites has acted lawfully. Given the serious medical questions involved, we must hope they have acted wisely as well.

meat products. See *Consumer Porduct Safety Comm'n* v. *GTE Sylvania, Inc.*, No. 79-521 (June 9, 1980), slip op. 21; *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council, Inc.*, 435 U.S. 519, 557-558 (1978). Petitioners have not cited a single decision in which an agency was required to engage in explicit fact-finding on the efficacy of labeling once Congress declared it a sufficient and appropriate means of protecting consumer interests.[6]

Petitioners particularly focus on "the plight of illiterates, non-English speaking consumers and those with infirm vision" (Pet. 13), and stress the inefficacy of labeling as a protection for them.[7] However, the Federal Meat Inspection Act, as amended, requires that mandatory label information be conspicuous "and in such terms as to render it

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[6]Of course, the Secretary must determine what type of labeling will be effective in a particular set of circumstances and will adequately protect the varied interests of consumers. However, as this Court observed in a different context, such determinations are "primarily of a judgmental or predictive nature * * *." *FCC* v. *National Citizens Comm. for Broadcasting, supra*, 436 U.S. at 813. Therefore, explicit fact-finding is not required and is often not possible. *Id.* at 814. In any event, in the instant case, as the court of appeals observed (Pet. App. 11-13), the Secretary not only "considered evidence of the effect of the proposed regulation, particularly the labeling requirements, on" the risk of botulism (*id.* at 11), he also responded to the " 'expressed concern [of some who commented on the proposal] whether such labeling provisions would be adequate to protect against botulism' " (*ibid.*) by requiring in the final rule that the term "uncured" be part of the product name of all nitrate and nitrite-free products, and by deleting (because of the confusion it was likely to engender) a proposed provision that would have permitted the sale under traditional product names of low-nitrate products labeled "Not Fully Preserved, Must Be Refrigerated Below 40° F. At All Times" (*id.* at 12). Thus, it is evident from the record that the Secretary carefully considered the efficacy of the particular labeling requirements set forth in the rule he promulgated. See also pages 7-8, *supra*.

[7]Such persons also would not be able to differentiate between traditional names and the new ones petitioners would have manufacturers of nitrite-free products adopt, or between products labeled "cured" or "uncured" and those labeled "imitation," a designation petitioners pressed in the district court (Pet. App. 41).

likely *to be read and understood by the ordinary individual* * * *." 21 U.S.C. 601(n)(6) (emphasis added). Statutory schemes for the protection of health, safety, and property quite commonly rest on the assumption that the ordinary person in this country can read English or will seek the aid of someone who can, and will act upon reasonable warnings and instructions.[8]

b. The court of appeals correctly rejected petitioners' claim (Pet. 22-23) that the rule here at issue was promulgated for the allegedly unlawful purpose of promoting the interests of nitrite-free product manufacturers at the expense of competitors who use the additive (Pet. App. 13-16). As noted above, the rule constitutes a measured response to the articulated desire of consumers and producers for products that they reasonably believe to be less injurious to health than products readily available in the market (*id.* at 53, 84). As the court of appeals recognized (*id.* at 14), the Secretary is obligated by statute "to ensure that the products desired by consumers be made available to them in a form and manner consistent with the public health and welfare. Every time the Secretary approves a product's ingredients or label, he, in one sense, is promoting that product. To be sure, the agency should not be promoting a particular company or a particular product of a particular company, but merely fulfilling consumer desires, while ensuring consumer health and safety, does not constitute unlawful promotion."

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[8]See, *e.g.*, Securities Act of 1933, 15 U.S.C. 77a *et seq.*; Automobile Information Disclosure Act, 15 U.S.C. 1231 *et seq.*; Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331 *et seq.*; Fair Packaging and Labeling Act, 15 U.S.C. 1451 *et seq.*; Truth in Lending Act, 15 U.S.C. 1601 *et seq.*; Interstate Land Sales Full Disclosure Act, 15 U.S.C. 1701 *et seq.*; Motor Vehicle Information and Cost Savings Act, 15 U.S.C. 1901 *et seq.*, especially 15 U.S.C. 1981-1989; Consumer Product Safety Act, 15 U.S.C. 2051 *et seq.*

In any event, even if the challenged rule expands the market for nitrate and nitrite-free meat products, petitioners need not suffer economic injury since they may compete in the expanded market by producing such products and complying with the new labeling restrictions. In fact, one-third of the members of the National Independent Meat Packers Association, plaintiff-intervenor below, already trade in products free of nitrates and nitrites (Complaint of Intervenor para. 2, A. 117-118). On the other hand, should petitioners prefer not to enter that market, they are free to continue business as usual. As the court of appeals observed (Pet. App. 16), "[u]nder the new rules, no meat packer is required to manufacture nitrate and nitrite-free products, no wholesaler is required to supply them, and no retailer is required to stock them. Furthermore, the production and sale of nitrate and nitrite-preserved products are unaffected. In short, * * * the regulations are a rational response to the legitimate requests of concerned consumers and were not promulgated for an unlawful purpose."

2. The court of appeals rejected petitioners' contention (Pet. 24-25) that the Secretary violated the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*, by failing to file an environmental impact statement (EIS) in connection with the challenged rule and by failing both to articulate his reasons for not doing so and to develop a record to justify his decision. In essence, the court concluded (Pet. App. 19-20) that since the proposed rule did not significantly affect the environment, an EIS was not required, and that the Secretary's determination that the proposed rule presented no significant health dangers (its only arguable environmental impact) was fully supported by the record. That

decision is correct and does not conflict with the decision of any other circuit.[9]

An environmental impact statement is required only when an agency proposes "major Federal actions significantly affecting the quality of the human environment." 42

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[9]Petitioners insist (Pet. 24) that the Second, Seventh, and District of Columbia Circuits "require a rulemaker who determines not to file a[n] * * * environmental impact statement (EIS) to assess all relevant factors considered in that determination, state its reasons for not preparing an EIS, and affirmatively develop a reviewable administrative record in support of the decision not to file an EIS." However, the cases cited by petitioners do not support so broad a proposition and do not conflict with the instant case. In *Nucleus of Chicago Homeowners Ass'n* v. *Lynn*, 524 F. 2d 225 (1975), cert. denied, 424 U.S. 967 (1976), the Seventh Circuit considered the contention, advanced by persons owning homes adjacent to part of a proposed scattered-site low-income public housing project, that HUD's decision not to file an EIS was not supported by a record sufficiently developed for judicial review. While concluding that "NEPA does require that an agency affirmatively develop a reviewable administrative record supportive of a decision not to file an impact statement" (524 F. 2d at 231), the court added that "the content and volume of such a record depend upon the particular federal action proposed. A concise statement may be sufficient to support an agency finding of no significant environmental impact if it is grounded on supporting evidence" (*ibid.*; citation omitted). It then reviewed the administrative record in much the same way as did the court of appeals in the instant case and concluded both that a satisfactory basis for judicial review existed and that HUD had properly determined that no EIS was necessary. In *Scientists' Institute for Public Information, Inc.* v. *Atomic Energy Comm'n*, 481 F. 2d 1079 (1973), the D.C. Circuit announced (*id.* at 1094) that when an agency "has decided that a NEPA statement is not yet necessary, it should state reasons for its decision." However, in the absence of any such statement of reasons the court "resort[ed] to other material in the record to determine whether the [AEC] properly decided not to draft a[n environmental impact] statement * * *" (*id.* at 1095). The third case on which petitioners rely, *Trinity Episcopal School Corp.* v. *Romney*, 523 F. 2d 88 (2d Cir. 1975), concerned a NEPA provision not at issue in the instant case and is thus inapposite.

Petitioners also rely on regulations promulgated by the Council on Environmental Quality, 40 C.F.R. 1500 *et seq.* (1979). However, as the district court noted (Pet. App. 45 n.3), those regulations were not promulgated until well after the rule challenged here was proposed.

U.S.C. 4332(2)(C). See *Andrus* v. *Sierra Club*, 442 U.S. 347, 350-351 n.2 (1979); *Kleppe* v. *Sierra Club*, 427 U.S. 390, 399-401 (1976). Petitioners' assertion (Pet. 24) that "[t]he present rulemaking [has been] conceded by the Department to be of [a] 'major' character" is misleading. The "Note" to the final rule cited by petitioners (Pet. App. 93) states that the rule is "significant" for purposes of the President's Executive Order on "Improving Government Regulations," Exec. Order No. 12044, 43 Fed. Reg. 12661 (1978), an Executive Order concerned with making federal regulations "as simple and clear as possible" (*id.* at Section 1). That determination has no bearing on whether the rule is a "major Federal action" for purposes of NEPA (42 U.S.C. 4332(2)(C)).[10] Moreover, we question whether a rule setting forth labeling requirements for food additives can affect the "environment" as that term is used in NEPA. See *Image of Greater San Antonio* v. *Brown*, 570 F. 2d 517, 522 (5th Cir. 1978); *Breckinridge* v. *Rumsfeld*, 537 F. 2d 864, 865 (6th Cir. 1976), cert. denied, 429 U.S. 1061 (1977); *American Meat Institute* v. *Bergland*, 459 F. Supp. 1308, 1315-1316 (D.D.C. 1978); *Township of Dover* v. *United States Postal Service*, 429 F. Supp. 295, 297 (D. N.J. 1977). In any event, the sole conceivable ground for concluding that the rule constitutes an action "significantly affecting the quality of the human environment"—namely the health risks it assertedly engenders—is, as the court of appeals held (Pet. App. 20), "unsupported" by the record.

Even if, as petitioners urge, the refusal to prepare an environmental impact statement must be buttressed by articulated reasons and a reviewable administrative record,

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[10]Although we do not dispute that the federal undertaking here was "major," if only in terms of its impact upon the affected industries, we note that the Eighth Circuit sitting en banc has cautioned against bifurcating the pertinent language of the statute and has concluded that "major

that requirement is met here. The possible health consequences of the rule were fully considered by the Secretary prior to its promulgation. In the Background Information section accompanying the proposed rule, he stated that "[b]ased on agency experience and expertise, it appears that [nitrate and nitrite-free] products would * * * be protected against botulism" by proper refrigeration or other preservative methods and that proper labeling, as proposed, would avoid any product confusion (Pet. App. 54-55). These conclusions were further elaborated in the Final Impact Statement, where the Secretary stated that "[t]his regulation is not expected to result in any increase in incidence of food poisoning from *Clostridium botulinum* toxin types A and B, those primarily associated with the red meats" (Pet. App. 80). Similarly, in the Supplementary Information section accompanying the final rule, the Secretary reviewed the rationale for the labeling requirement, considered the concerns expressed in various comments, and again concluded that no significant health risk is posed by the rule (*id.* at 84-91). Thus, even assuming *arguendo* that the Secretary was required to explain why he did not prepare an environmental impact statement, he substantially fulfilled that obligation here, as the court of appeals correctly held (*id.* at 19-20). See *Minnesota Public Interest Research Group* v. *Butz*, 498 F. 2d 1314, 1320 (8th Cir. 1974) (en banc).

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federal actions" and "significantly affecting the quality of the human environment" should not be read as separate or independent tests. *Minnesota Public Interest Research Group* v. *Butz*, 498 F. 2d 1314, 1321-1322 (1974).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

WADE H. MCCREE, JR.
Solicitor General

ALICE DANIEL
Assistant Attorney General

ROBERT E. KOPP
AL J. DANIEL, JR.
Attorneys

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No. 80-742

In the Supreme Court of the United States

October Term, 1980

NATIONAL PORK PRODUCERS COUNCIL, CHARLES GRASSLEY, THOMAS HAGEDORN, and STEVEN SYMMS,

Petitioners,

vs.

BOB BERGLAND, Secretary of Agriculture, CAROL TUCKER FOREMAN, and DONALD H. HOUSTON,

Respondents.

On Petition for Writ of Certiorari to the Court of Appeals for the Eighth Circuit

REPLY BRIEF IN SUPPORT OF PETITION

DONALD P. COLLETON
Counsel of Record

JAMES L. FOX
ABRAMSON & FOX
One East Wacker Drive
Chicago, Illinois 60601
(312) 644-8500
Attorneys for Petitioners

UNITED STATES LAW PRINTING CO., CHICAGO, ILLINOIS 60618 (312) 525-6581

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REPLY BRIEF IN SUPPORT OF PETITION

The government obscures the Rule's grave jeopardy to human health to minimize the rulemaker's lack of requisite attention to factors relevant to that jeopardy.

In truth the Rule creates a consumer trap. It permits, for example, uncured product to be formulated in lengths, shapes and colors *identical* to those of real hot dogs, to be marketed in double decker 10 packs now associated with real hot dogs, to bear "keep refrigerated" instructions now

appearing on real hot dog labels, to be packaged in wrapper colors, styles and logos currently associated with the processors of real hot dogs, to be merchandized in retail coolers adjacent to, or indeed within, stacks of real hot dogs, and to include the traditional name "hot dog" on the label. The consumer's only tip-off to this deadly trap is the presence of the term "Uncured" and the indication that the preservative nitrite is absent.

It may well be appropriate, where there is no health hazard from confusion of product identity, to indulge in a working hypothesis that ordinary consumers will read labels under ordinary circumstances. That hypothesis, however, much less the irrebutable presumption in reality urged by the government, has no place where the circumstances promoting confusion are anything but ordinary, where the ordinary consumer as well as the illiterate, the non English speaking consumer and those with impaired vision will be equally unprotected, and where the health risk from confusion could be death.

I.

Wrong Standard of Review

The government in effect claims that judicial scrutiny of the rulemaker's inattention to the label adequacy issue, Pet. 12-18—an undeniably "relevant factor" under *Citizens to Preserve Overton Park* v. *Volpe,* 401 U.S. 402 (1971)—has been greatly limited if not completely foreclosed by a "legislative determination", Br. Op. 9, that labeling "is" an "effective means of protecting consumers." *Id.* As a consequence, argues the government, no "explicit fact-finding", Br. Op. 10, n. 6, is required on the question of the adequacy of the present label to prevent deadly botulism, and, in any event, for purposes of testing the sufficiency of the challenged rulemaking it must be

assumed, by virtue of a definition of adulteration in the Federal Meat Inspection Act, 21 U.S.C. §601(n)(6), that "the ordinary person in this country can read English or will seek the aid of someone who can, and will act upon reasonable warnings and instructions." Br. Op. 11

Applicable law permits no such approach. It is now common ground that a label cannot stand if deception, injury or confusion would be likely but for an unsupported *assumption* that consumers will read explanatory information on it. *Houston* v. *St. Louis Independent Packing Co.*, 249 U.S. 479, 487 (1918); *Federation of Homemakers* v. *Butz*, 466 F.2d 462, 465-466 (D. C. Cir. 1972); *Cf. Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, 230-231 (1943). USDA therefore like any other agency was obliged to consider the adequacy of the presently assailed label, develop an adequate administrative record supporting necessary findings on this issue, and draw conclusions rationally supported by those findings. At a minimum this would include an articulated explanation of its basis for concluding, if it so concludes, that illiterates, non-English speaking persons, consumers with impaired vision and the like[1] as well as ordinary persons unacquainted with the nitrite controversy will be adequately protected against botulism under the look and name alike circumstances created by the Rule.

Were the government correct that inadequacy of explanation is acceptable in labeling cases, *contra, Citizens to*

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[1] Section 601(n)(6) of the Federal Meat Inspection Act provides no more than that labeling mandated by the USDA shall be considered misbranded if not presented so as likely to be read and understood by ordinary individuals. It does not follow from this that Congress has authorized USDA to create circumstances which place large subclasses of the population at deadly risk of botulism merely because these consumers might not be classified as "ordinary."

Preserve Overton Park v. *Volpe, supra; National Nutritional Foods Ass'n.* v. *Weinberger,* 512 F.2d 688, 701 (2nd Cir.), *cert. denied,* 423 U.S. 827 (1975); *U. S.* v. *Nova Scotia Food Products Corp.,* 568 F.2d 240, 251 (2nd Cir. 1977), and that labels are legislatively presumed to be efficacious, USDA could, viewing the present situation in its limits, without rational basis authorize the inclusion, in a familiar appearing food, of a substance highly toxic to all but a few consumers as long as this fact were disclosed on the label. But that is exactly what the government is urging here when it insists that USDA was under no obligation to consider whether, and explicitly to state its conclusions and bases therefor that, *ordinary* American consumers, much less illiterates and other special classes mentioned in the Comments, would read and understand the label of a product which appears to be entirely familiar and hence needing no label inspection.[2] Until such an explicit statement is provided "in the [challenged] order . . . itself", *Burlington Truck Lines* v. *U. S.,* 571 U.S. 156, 169 (1962), that is "in the 'Statement of the Bases and Considerations' filed with the adopted regulations", *Angel* v. *Butz,* 487 F.2d 260, 263 (10th Cir. 1973), *cert. denied,* 417 U.S. 917 (1974), the court cannot conduct the review mandated by the Administrative Procedure Act, see *Citizens to Preserve Overton Park* v. *Volpe, supra; National Nutritional Foods Ass'n.* v. *Weinberger, supra,* and has no choice but to set the rulemaking aside.

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[2] The government's observation that "the Secretary must determine what type of labeling will be effective", Br. Op. 10, n.6, seems meaningless against the conjunctive observations that "explicit fact-finding [regarding labeling efficacy] is not required", *Id.* and that the efficacy of labeling has already been legislatively determined. Br. Op. 9. That formulation is a blueprint for arbitrary, unreviewable conduct. It permits the agency to assert without reason or analysis conclusions quite literally, as here, of life and death import which, because of their presumed propriety, escape judicial review.

The suggestion that USDA implicitly responded to the crucial labeling questions raised in the Comments by requiring the term "Uncured" in the challenged labels, Br. Op. 10, n. 6, does not rectify the shortcoming. For reasons just given, USDA's considerations must be, but are not here, sufficiently explicit to permit requisite judicial scrutiny. Of equal importance is the fact that there is no rational support in the record for a conclusion, were it stated, that inclusion of the term "uncured" would reasonably protect either the special classes referred to in the Comments or the general consuming public. Pet. 16-17.[3]

II.

Post Hos Rationalizations Cannot Justify the Rule's Unlawful Purpose

In answer to Petitioners' contention that the Rule was promulgated for an unlawful purpose, Pet. 22-23, government counsel say:

> "the Rule constitutes a measured response to the articulate desire of consumers and producers for products that they reasonably believe to be *less injurious to health* than products readily available in the market." Br. Op. 11

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[3] The government seemingly concedes the Rule's vulnerability when it acknowledges that illiterates, non-English speaking consumers and those with infirm vision will not be able to differentiate between certain label names including, for example, "hot dog" and "uncured hot dog." Br. Op. 10, n. 7. Even more pertinent is the fact that these are the very consumers who, not being able to "read" labels prescribed by the Rule, will rely on the similarity of physical characteristics, e.g., color and size, mandated by the Rule and familiar packaging wrappers and logos permitted by the Rule in reaching the mistaken conclusion that uncured products are the traditional, cured variety.

The health injury involved is, according to counsel, the supposed carcinogencity of nitrite. Br. Op. 3, 4, 5, 7, n. 5. The court of appeals put it this way:

> "[T]he agency found persuasive evidence that the *benefits of the regulation* would outweigh any potential safety problem." App. 11

The problem with these characterizations of the Rule's purpose is that neither they nor any other mention of cancer, carcinogencity of nitrites, comparative health risk, or health related benefits of nitrite-free food appear in the Rule's statement of bases and purpose, App. 83-91. They are at bottom nothing more than *post hoc* rationalizations by counsel and the court of the Rule's purpose which, under settled law cannot be considered by this Court. See Pet. 22, n. 13

III.
NEPA Has Been Disregarded

Even if, *contra*, Pet. 24-25, the Department's Final Impact Statement, App. 72-88, were thought to satisfy NEPA's requirement that the Rule's public health impact be assessed, the FIS conclusion that the Rule

> "is not expected to result in any increase of food poisoning from *Clostridium botulinum*"

because the spores producing that poison

> "do not generally grow at temperatures below 40°F", Br. Op. 15; App. 80

is arbitrary and irrational. The crucial inquiry was whether an increased incidence rate was likely should uncured products be handled as their traditional, cured counterparts now are at 70°, 80° and 90°F for prolonged periods in the home, on picnics and camping trips, and in lunch pails and school lockers. See Pet. 19. Contrary to the requirements of NEPA, the FIS never addressed that question.

IV.

Conclusion

In a real sense review and reversal by this Court is the consumer's last hope of protection from the deadly trap created by the Rule. Wherefore, Petitioners respectfully request that the writ issue.

Respectfully submitted,

DONALD P. COLLETON
JAMES L. FOX
Attorneys for Petitioners,
National Pork Producers Council
Charles Grassley, Thomas Hagedorn
and Steven Symms

Of Counsel:
ABRAMSON & FOX
One East Wacker Drive
Chicago, Illinois 60601
(312) 644-8500